A The expiration date on the bottle, on the product. This letter --

MR. BLIZZARD: This is the original exhibit, so if we could switch out.

MR. PETTIT: I'll show you the original, and then I can mark up this one.

BY MR. PETTIT:

Q Were you going to finish saying something? It sounded like you were saying something else.

A I was just commenting that the document -- this is a letter that Mylan sent out, not Actavis.

Q I understand that.

A Oh, okay.

Q But you sent it, meaning Actavis sent it over your signature, to Mylan?

A Yes.

Q And then do you have any knowledge, personal actual knowledge that Mylan sent this letter out?

A Product came back. So I'm not sure

what your question is.

Q My question is whether or not products came back for some reason. Do you know whether this actual letter went out from Mylan to someone else?

A I would not be -- I wouldn't participate in that activity, so no.

Q Did you ever ask anyone at Mylan or did Mylan ever tell you that it went out?

A Yes.

Q Who did you speak to at Mylan?

A I didn't speak to anyone directly, but the information was conveyed back to me mainly because that's why I recognize Stericycle, because the product that they were bringing back went to a different third party for the recall. So ours was -- if you look at my original draft, that information for the return is different.

Q And just because this is a different numbered exhibit, you're looking at the third page -- or the second page of the document?

A Yes.

Q And that's your signature; correct?

A No, that's not my signature.
Q Someone signed for you?
A Someone -- I don't recognize the signature. It says someone's name for and it uses my name, but it's not my signature.
Q Is that a practice that you followed at some point in 2008, that someone could sign a formal document?
A As I said before, this appears to be -- it appears to me that this document was Mylan's document, that it was altered to include their information. And I don't recognize the signature.
Q Okay. I'd like you to take as long as it takes for you to read that one-and-a-half-page letter and tell me if there's anything in it that you would not sign sitting here today.
A That I would not?
Q That you would not sign, that there's something that you would be unhappy that your signature was, in fact, on the second page.
A It doesn't have the attachment with

the lot numbers. But other than that, it seems to be a document that I would sign, yes.

Q Okay. And you're referring to the fact that Exhibit 113, which Mr. Blizzard showed you, had a list of the batches; correct?

A Yes. And this refers to the -- actually it says the product labels, but they're not attached.

Q But the actual substance of this one-and-a-half-page letter is correct and accurate?

A Yes.

Q Now, if this letter went out around April 30th or May 1st, somewhere in that time period, that would be three weeks after you made a commitment that there was a probable Digitek recall on April the 9th, 2008; correct?

A The timing you're referring to is correct, but my statement was to a colleague about where I thought we were headed with the digoxin review.

And from what I can recall, that

time period after -- there were a number of other products that the Agency was looking at that Actavis committed to recall. And that pretty much wrapped up around April 9th where I put it in writing that we were going to recall those other products.

When we got to that point, Erin had moved off of those products and was starting to look at other products, Digitek being one of them. So April 9th was when -- around the time frame when she started to look at the Digitek and question the investigation associated with the batch with the so-called double-thick tablets.

So there was no commitment to recall that batch until probably at least a week or so later because there was a number -- there were --for one thing, she was asking for more information, and we were providing information to her. And we were still in the -- in the mode of trying to, I guess, satisfy her concerns.

Q Are you retracting any of your testimony to Mr. Blizzard today about whether

there was a probable Digitek recall, in your mind, as of April 9, 2008?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: I would have to look back at what exactly I wrote, but I said it's probably a recall. But that, again, is a statement I made to a colleague. It is not a formal commitment to FDA to recall something. There's a big difference.

BY MR. PETTIT:

Q In your mind -- are you finished your answer? I'm trying not to speak over your answer.

A Yes, yes.

Q In your mind, on April the 9th, 2008, it was already probable that there would be a Digitek recall --

MR. DEAN: Objection.

BY MR. PETTIT:

Q -- is that correct?

MR. DEAN: Objection; misstates the testimony, misstates the document.

Do you want to look at 107?

THE WITNESS: Yes.

It was --

BY MR. PETTIT:

Q Now that Mr. Dean has coached you on answering the question --

MR. DEAN: I showed her the document. You're the one who's misstating it.

MR. PETTIT: Counsel, there is not only no speaking objections, there's no shoving documents in front of the witness. I mean, I don't know what court you practice in. I've never seen such a thing.

MR. DEAN: I've never seen an attorney try to trick a witness and say she's testified to one thing when she hasn't testified to it at all. I think it's only fair to show the witness the document. I think, in fairness, you're probably confused about the document.

MR. PETTIT: All right. Now you've totally coached your witness on

what to say.

BY MR. PETTIT:

Q So let me put the document that does not have the oral testimony that you gave Mr. Blizzard on it; but I will show you the document, now that Mr. Dean has put it in front of you, so the jury can see what your lawyer -- excuse me -- what Actavis' lawyer put in front of you. And I'm going to let the jury look at it, and then I have to hand it back to you. Okay?

Now, does that help you in answering your question -- answering my question, which was whether or not you choose now to retract any of the testimony you gave to Mr. Blizzard today about the fact that, in your mind, on April the 9th, 2008, there was probably going to be a Digitek recall?

MR. DEAN: Objection. That's a different question than what you asked her before.

Go ahead.

THE WITNESS: I don't retract anything I said before. I never said --

I am putting it in the context of what is written here and the intent of it. Erin looked at the investigation and was not -- visibly not pleased with it. My comment to my colleague was that I thought it was going into that direction.

But in terms of actually what had happened was that we spent several days giving her information to help clarify the issues, which turned out to be unsuccessful.

So it was not a formal commitment to the FDA to recall anything until at least a week later.

BY MR. PETTIT:

Q On April the 9th, 2008, Actavis had no plans to recall Digitek and they were waiting for the FDA to pressure them into doing it; is that correct?

MR. DEAN: Objection; argumentative.

Go ahead.

THE WITNESS: No. It was the beginning -- in any of these instances,

the FDA is reviewing something and there's supplemental information that can be provided to clarify issues, to satisfy concerns. And it became clearer as we moved on that nothing -- there was nothing that was -- I had testified also earlier that I had no experience with what she was looking at. I didn't participate in it. I was not actively involved in it.

So as a responsible individual, I needed to look into the issues and provide her with the information and the people for her to question so that she could fully understand it. No company is going to jump up and recall something the first time FDA reviews it and says they don't like it.

BY MR. PETTIT:

Q Do you think that April 2008 was the first time the FDA reviewed this Digitek problem?

MR. DEAN: Objection to form; vague and ambiguous.

Go ahead.

THE WITNESS: I don't know the exact date, but it was early April when she first started to look at the digoxin batches, yes.

BY MR. PETTIT:

Q As the vice president of quality and compliance, from September 2007 to April 9th, 2008, did you make an effort to find out if the FDA was concerned about the release of the batch that we've been talking about that had the double thickness?

A Why would I do that? FDA didn't know that batch existed until they came on-site in March and subsequently picked up a batch record, saw it, and looked at the investigation. That was the first time I saw it.

Q Did you make any effort, as the vice president for quality and compliance, to inform the FDA that there had been a batch of 4.8 million pills of Digitek released after there had been an inspection, which was 07-093 inspection?

MR. DEAN: Objection; assumes she had knowledge of it.

Go ahead.

THE WITNESS: As I stated before, I had no knowledge of this issue until FDA looked at the batch record during the inspection in 2008.

BY MR. PETTIT:

Q Did you ever criticize Mr. Bitler for not consulting you about his decision to release that batch?

A No, I don't believe so. And there was also another director in between -- Dan did not report directly to me.

Q Did you ever criticize Scott Talbot for not telling you?

A Not necessarily because the day-to-day operations really fell into the site quality purview. And I would typically not be consulted on every issue. I would have liked to have been consulted in this particular case, but there was no criteria for which they needed to notify me.

Q Which was my next question. Is

there a written policy or criteria for when Mr. Bitler would tell Mr. Talbot or when -- strike that.

Is there a written criteria or policy for when Mr. Talbot would inform you of a decision to release 4.8 million pills in a batch where there had been double-thick tablets found?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: There was no criteria of any sort at that time.

BY MR. PETTIT:

Q When you say you would have liked if Mr. Talbot had informed you, was that your thought in April 2008?

A When I saw the investigation, yes, I would have liked to have been consulted on it.

Q And did you wish that there were an Actavis criteria or policy in place to make Mr. Talbot talk to you about release of that batch?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: I can answer?

MR. DEAN: Sure.

THE WITNESS: Even with guidelines for communication and elevating of issues, it would be difficult for any site to run where the VP of all of US operations had to be consulted on every decision.

So I do agree that there should be criteria, and I believe there were subsequently procedures put in place so that things of a certain nature would be elevated to my level. But it's still never practical for it -- it would never always be on every batch or every decision.

BY MR. PETTIT:

Q But, in fact, it was possible to have done it if Actavis had chosen to do it?

MR. DEAN: Objection.

Go ahead.

BY MR. PETTIT:

Q To have such a policy in writing.

A You could never outline every

instance in which you want to get a phone call. So I don't think anybody was going to write into any SOP that if you have double-thick tablets and you want to release the batch after inspection, that you have to call the VP.

You're being very specific in your questioning.

Q Was there anything in your CAPA afterwards, after the April 2008 -- March and April 2008 inspection that suggested there be such a criteria?

A There was no such criteria as far as I know. But what it did enable was just more visibility about what was going on at the site in terms of the investigations that were being opened and closed and the nature of those investigations, which would allow reporting and visibility to the issue so that if there was something, I could question it or any VP in my role or anyone in my role could question it.

Q Are you finished your answer? Because I don't want to speak over you.

A Yes, uh-huh.

Q I'm going back to Exhibit 120, which is up here on the screen, the April 28th, 2008, letter that Actavis sent to Mylan. And at the very beginning, it talks about the recall. It says: "This recall has been initiated due to overweight tablets."

Do you see that?

A Yes.

Q And that, in fact, is accurate; is that correct?

A I'm trying to remember where that wording came from. And I don't recall, but that was what was agreed upon as the reason for the recall.

Q Agreed upon among others by Actavis?

A Yes.

Q And agreed upon by yourself as well personally while you were vice president at Actavis?

A Yes.

Q There -- well, let me ask it a different way.

Were there letters that were drafted

by Actavis that were intended for pharmacies to send to the patient or the consumer about the recall?

A For Digitek?

Q Yes, about the Digitek recall.

A I don't think so, not to my knowledge.

Q Were there -- without speculating, were there letters drafted by Mylan -- drafted by Mylan that were intended for use by the pharmacies to send to consumers or patients?

A I don't know.

Q Did you ever ask how the consumer or the patient was going to learn about the recall? Did you ever ask anybody at Mylan?

A No.

Q Did anybody at Mylan ever talk to you about what their intentions were so that the consumers and the patients could find out about the recall?

A No.

Q Did Actavis ever do anything to find out if the pharmacies were sending letters to the consumers?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: I know that there were several other groups of people that were coordinating these efforts, but I was not directly involved.

BY MR. PETTIT:

Q Do you know who that was?

A More along the lines of customer service groups so that they could answer questions and handle information because people were calling and not -- if they were Mylan's customers, we had no familiarity with them.

So I know that the customer service groups had to work together to help answer questions and direct the product to the right locations. But I didn't participate in that directly.

Q Mr. -- I'm moving on to another topic.

Mr. Blizzard asked you some questions about risk assessment. And I want to ask you, is there something different

called a health hazard assessment?

A Actually we talked about a health hazard assessment this morning.

Q Correct.

A Yes.

Q And Mr. Blizzard -- I don't want to try to characterize what he said and what you answered. That's what actually I'm trying to find out now.

When you were talking about a health hazard assessment this morning to Mr. Blizzard, in your mind, is that different than something called a risk assessment?

A Yes.

Q Okay. What's the difference?

A I think a health hazard assessment is one form of a risk assessment, but there are other types of risk assessments that are not always health hazard-related.

So, I mean, I don't know if that answers you, but that kind of puts it -- I put it in two different categories.

Q Again, somewhat paraphrasing what you said, I think you said that you did not

know if there was a health hazard assessment done for Digitek; correct?

A Correct.

Q Do you know, sitting here today, who might likely know that at Actavis if there were one done?

A If there were one done, the pharmacovigilance group.

Q And who is that? I mean the names of people.

A Sarita -- I don't know her last name.

Q Spell Sarita for us, please.

A S-A-R-I-T-A.

Q What was her title or her approximate title?

A I don't know if she's director or manager of pharmacovigilance.

Q What department?

A Regulatory affairs. Pharmacovigilance is a department name, and it falls under the regulatory affairs group.

Q Do you know if she's still at Actavis?

A I don't know.

Q You were speaking to Mr. Blizzard earlier this morning about some duties that you had after the recall. And one of the things that he and you were speaking about was something called refresher GMP training?

A Yes.

Q And that's good manufacturing practices?

A Yes.

Q Were there any refresher GMP training sessions prior to the recall regarding Digitek? Well, strike that. I'll ask you a completely different question.

Prior to the April 2008 recall, were there any refresher GMP training sessions --

MR. DEAN: Objection.

Go ahead.

BY MR. PETTIT:

Q -- as of the time that you began there in September of 2007 up to April of 2008?

MR. DEAN: Let me state the basis of my objection; lack of foundation

with this witness.

Go ahead.

THE WITNESS: GMP training is done site-specific. And I'm not sure what the schedule was for that training, but you typically would do periodic training. So you would be trained upon employment, and then everyone would get updated, ongoing training at regular intervals on different topics or a general GMP training.

BY MR. PETTIT:

Q "Typically" meaning it should happen, or "typically" meaning you know for a fact that it did happen?

A I could not answer with respect to this site because I do not know what the -- I don't know the detail in the SOP.

Q If there were GMP refresher training -- refresher GMP training from September 2007 to April 2008, what department would cause that to happen?

A There was a training department. It was a training person on-site.

Q Was that under regulatory or under quality or something else?

A In this particular case, it fell under the quality organization.

Q Which is your organization?

A Yes.

Q Do you just not know because you delegated that job to someone else, or do you just not know period or what?

A Again, I was the head of all US operations that had multiple facilities. So I don't know the details of the SOPs in every facility.

As a matter of fact, one of the directions that we were going in at the time was to consolidate and make some of those practices consistent across all of the facilities.

Q I'm going to go on to a different topic. I want to ask you a couple questions about the recall.

Did you personally ever have a session where you orally spoke to the employees at Actavis or some of the employees

at Actavis to tell them what the reason was for the recall, the Digitek recall?

A The whole entire --

Q No. I'm assuming it would be smaller groups.

A So now ask me the question again.

Q Sure. Did you personally ever give any session where you orally presented to some of the Actavis employees what the reason or reasons were for the Digitek recall?

A Not that I can recall.

Q Did that happen by somebody else, if you know, without guessing?

A I believe there were discussions about what was going on at the facility in employee meetings, so updates to the employees as to the status of the inspection and what was going on. Recalls were part of that discussion to let people know. Specifically when we stopped manufacturing, there were a number of times that the employees were brought together, but I didn't give those presentations.

Q Do you know whether any of those

presentations presented the reasons for the Digitek recall?

A I don't know for a fact.

Q Have you ever heard of a pharmaceutical company stop making all of its products after an FDA inspection?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: Yes.

BY MR. PETTIT:

Q What other companies?

A There was a facility -- several -- two facilities that Schein owned that stopped manufacturing product.

Q All of its products?

A Yes.

Q Any others?

A There are other facilities that I have not worked at that were in the news and trade press that had resulted in a stop of manufacturing.

Q Of all their products?

A Yes.

Q How many? How many companies?

A I can think of at least two others.
Q Any others besides Schein and the two others?
A That's all I can recall right now off the top of my head.
Q And is that in your entire career?
A That's what I can remember now.
Q Stretching back over your entire career?
A Yes.
Q Do you know whether the consumers or patients that took Digitek were ever offered a refund by Actavis after the recall?
A I don't know.
Q Do you know who would most likely know that at Actavis?
A As I mentioned earlier, there were customer service representatives that were working in conjunction with those representatives from Mylan to answer customer-related issues and inquiries about the recall. So I don't know if -- typically in a recall, there's some instruction as to what to do with the product and whether they

would be reimbursed or whether product would be replaced, et cetera. I don't know the detail of this one.

Q Are you talking about a third party when you talk about customer service people or are you talking about Actavis?

A Both, both.

Q Who at -- if I wanted to, for example, take a deposition of someone at Actavis who most likely would know about a refund program, who do you think that would be?

A It would be -- I'm guessing that it would be somebody in the customer service department.

Q Of Actavis and you just don't know the names?

A Right.

Q Would you agree with me that but for the FDA inspection in March and April of 2008, Actavis would not have recalled Digitek?

MR. DEAN: Objection; calls for speculation.

Go ahead.

THE WITNESS: I would say that's probably true.

BY MR. PETTIT:

Q Are you able to estimate what percentage of all the batches produced by Actavis in New Jersey in 2007 were batches of Digitek?

MR. DEAN: Objection; lack of foundation.

Go ahead.

THE WITNESS: I don't know.

BY MR. PETTIT:

Q Do you have any sense at all?

A I only know that it was one of the higher-volume products due to the number of tablets in the batch size but not necessarily the number of batches, if that makes sense.

Q In going through documents, I have seen references to the batch that we've been talking about, which is the batch that they found the, quote, double-thick tablets in. And I have seen references to 70924, 70924A, 70924A1, and 70924A2.

Have you made any effort to find out

if all or some of those batch numbers were, in fact, the ones that were involved with the discovery of the 20 tablets and the investigation of it?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: I believe it's all the same batch. It's just a -- it's just a -- it gets the letters and numbers at the end as it's being processed through the -- it goes from manufacturing into packaging.

So it's given a batch number in the manufacturing. And then in some cases product is packaged into more than one container size. So then it gets different designations on the ends to distinguish different parts of the batch being packaged, perhaps hundred-count versus 500-count versus a larger size.

So it's all the same batch. It's all the same manufactured batch. The letter designations and the number designations at the very end are just

distinguishing between different packaging sizes, from what I can recall.

BY MR. PETTIT:

Q So if the batch that we're talking about were about 4.8 million tablets, it's your understanding that that is the sum total of the batch and there wouldn't be two separate batches with one of these other designations that I just listed?

A Correct. No two batches have the same number, not the same batch number.

Q So there could not be such a thing as a Batch 70924A1 and also a Batch 70924A2?

A They're both the same manufacturing batch. They are just designated as A1 and A2 because they're packaged in different container sizes.

Q So if there were 4.8 million tablets that were packaged differently, there would be less than 4.8 million in A1 and less than 4.8 million in A2?

A And when you add them together, they would be 4.8.

Q So when the many documents refer to

four different designations, is it your testimony that people meant to refer to just the same batch?

A Yes.

(Plaintiff's Exhibit No. 121 was marked for identification.)

BY MR. PETTIT:

Q Now, this is what is called a redacted document. I'm zooming out so the jury can see the entire document. And at the top are columns that say "Product," "Date Letter Sent to Capital Returns," "Date Letter Mailed to Customers," and "Comments." And the part that's not redacted says the Product: Digoxin Tablets; the Date Letter Mailed to Customer is April 29th, 2008.

Now, first of all, have you ever seen this actual document before just now? And I don't know if you can recognize it with the redaction, but I'm going to ask it anyway.

A I honestly can't recognize it.

Q Without guessing, do you know what it means?

A Yes. It's a list that indicates

when we sent the -- Capital Returns was the third-party group that we were working with to handle the recalls. And so it's saying here that we sent the final version of the recall letter to them on the 28th and that they mailed it to the customer on the 29th.

Q The customer, again, meaning Mylan?

A Correct.

MR. PETTIT: Go off the record for a second?

THE VIDEOGRAPHER: Off the record, 3:19.

(Discussion off the record.)

THE VIDEOGRAPHER: Back on the record, 3:21.

(Plaintiff's Exhibit No. 122 was marked for identification.)

BY MR. PETTIT:

Q Ms. Lambridis, I've shown you a document which I've marked -- is it 122?

A 122.

Q Thank you. My first question is: Have you had a minute to just glance through it? And tell me if you've ever seen it before

just now.

A I've not seen it in this exact format, but I've seen something similar.

Q And can you tell the jury what it looks like to you?

A It looks like a log of what investigations were opened on a monthly basis.

Q So what the jury's looking at right now is just the top page, July 2006; correct?

A Uh-huh.

Q August, September, October, and so on; correct?

A Yes.

Q And can you turn to Page 1423204, which is December 2007. And can you see that there's an investigation 07-093?

A Yes.

Q And there's a column in the beginning that says "Investigation Open By Department." And this one says "Manufacturing"?

A Yes.

Q And there's an "Investigation Initiated Date" and a "Disposition Approved

Date"; correct?

A Yes.

Q Now, do you know, without guessing, what that line means: 07-93, manufacturing department opened an investigation on December 5th, 2007, 1/25/2008?

First of all, I said that in a sentence. So is that sentence even correct? Can you put those words together and make a sentence like I just did?

A By looking at the column headers, I can say that there was an investigation opened on December 5 by the manufacturing department and it was given an investigation number, 07-093.

Q If -- first of all, do you recognize that number, 07-093, as a specific investigation?

A No.

Q Have you ever seen 07-093 as an investigation regarding a batch of Digitek which had tablets that were out of specification?

A If you're referring to the batch

that is under discussion, I actually read excerpts from that investigation report during the FDA inspection. But I wouldn't recognize that as the number.

Q If that were an inspection number for an inspection for an out-of-spec --

MR. DEAN: You mean investigation?

MR. PETTIT: What did I say?

MR. DEAN: Inspection.

MR. PETTIT: I'm sorry. Thank you.

BY MR. PETTIT:

Q If that is a number for an investigation for an out-of-spec Digitek batch, a batch of Digitek where there were some out-of-spec Digitek tablets, is it unusual for the department that opened the investigation to be manufacturing?

A No. It would depend on what the issue is. Whoever -- it varies from company to company, but typically where the event occurred is where -- the department given the responsibility for the investigation, to open

it and to conduct it. Sometimes it's found by another department, but it would still go back to where it originated.

Q So if 07-03 were an investigation number for that batch of Digitek that we've been talking about all day, even if the inspection were handled by Mr. Bitler out of the quality group, it could still be opened by manufacturing; is that correct?

A Yes.

Q And do you have memory, from this document refreshing your memory or not, as to whether those dates are correct for the inspection, without guessing?

MR. DEAN: For the investigation?

MR. PETTIT: I'm so sorry.

BY MR. PETTIT:

Q "For the investigation" is what I mean to say.

A I am not that familiar with this format. I'm not sure what you're asking me. Do you want me to verify that those are the dates?

MR. PETTIT: No. It's a bad question, so let me make it a smaller question.

BY MR. PETTIT:

Q Separate from this document, do you have any knowledge as to the beginning date and ending date of the inspection Mr. Bitler did on that batch?

A No.

Q If this is an accurate document for investigations opened in December 2007, does that refresh your recollection, without making a guess?

A I don't have that knowledge.

Q And would Mr. Bitler be a good person to ask when that investigation was opened and closed?

A Yes.

Q Would there be anybody else that I could ask that question to?

A Mr. Talbot.

Q Anybody else?

A Not that I'm --

MR. DEAN: You should speak up.

THE WITNESS: No.

BY MR. PETTIT:

Q So Mr. Talbot and Mr. Bitler would be the two most knowledgeable people about the beginning and ending date of that investigation?

A Yes.

Q There was plan to move some or all of the Little Falls manufacturing operations to Riverview; correct?

A Yes.

Q Was it some of the Little Falls production operations or all of it? What was the plan?

A I believe the plan was for all of it to move.

Q And obviously that would mean that all of the Digitek production -- the plan was to move all of the Digitek production to Riverview; correct?

A Correct.

Q When -- well, you got there in September 2007. Do you know if that plan was already in place when you arrived?

A Which part of the plan?
Q The plan to move all of the Digitek production from Little Falls to Riverview.
A It was already in --
Q The plan was in place, not the --
A The plan was in place, yes.
Q -- not the finality of it?
A Right.
Q Do you know when the plan began?
A No.
Q Was the plan to have Little Falls continue to manufacture some Digitek, or would that end and then a hundred percent of the Digitek would be produced at Riverview? What was that plan?
A I was not there when all of the plans were made, but it was my understanding that all of the operations would move out of the Little Falls facility at some point in time. So there would probably be manufacturing going on in both places for a while until they could close the Little Falls facility and have everything all set in the other facility.

Q What was the reason for the plan to move all of the manufacturing operations for Digitek to Riverview?

MR. DEAN: Objection; no foundation.

Go ahead.

THE WITNESS: As I said before, I was not part of the discussions regarding the rationale behind it all. But from what I do know, it was to handle the increase in the number of products and also because the Little Falls facility was leased and the Riverview facility was owned.

BY MR. PETTIT:

Q Where did you learn those two possible reasons? Was that from speaking to someone?

A Just from discussions, just from discussions.

Q With whom? My point being if I wanted to take someone's deposition on that issue, who would be a good person to ask?

A It was part of general meetings, so

I would say the operations group, the senior management at Actavis.

Q Mr. Dowling?

A I don't -- I would think it would be more along the lines of above that level, more of a higher level with --

Q Can you give me a name?

A Chris, Chris Young; Jeff Rope; Apurva; at the time it was Steinthor.

Q Apurva Patel?

A Patel. Steinthor, who was actually the most senior person in operations at the time.

Q Do you know, without guessing, whether there were any backlogs or backorders for Digitek in the fall of 2007 when you arrived?

MR. DEAN: Objection; no foundation.

Go ahead.

THE WITNESS: I don't know the answer to that.

BY MR. PETTIT:

Q Who would be the person or persons

who you think would have knowledge about that if I wanted to ask them?

A People in supply chain.

Q Is that a department?

A Yeah. It's the plan -- basically the planning department and the department that coordinates the orders for material with the delivery dates. They work with production and plan out the production schedule.

Q Since I'm looking for names, I at least need a department that I can recognize in these documents. I was wondering if that's a department I can look for or are they in some other department?

A Regarding backorder?

Q Backorders or backlogs for Digitek in 2007.

A Bharat or Dhaval.

Q Spell those for me.

A B-H-A --

Q Do you need a piece of paper to scribble?

A No. That's all right.

B-H-A-R-A-T. And the other was

Dhaval, D-H-A-V-A-L, I believe.

Q And I'm sorry to ask it this way, but are those first names or last names?

A Those are first names.

Q Do you know the last names?

A I'm not sure.

Q And not to repeat the question too many times --

A No. That's okay. Go ahead.

Q Are they in a department that I can look at a department organizational chart?

A It varies what they call that group from company to company, but it would be the planning department or the supply chain logistics department.

MR. PETTIT: I'm sorry. That's already been marked. That will confuse the record. Just void that out.

BY MR. PETTIT:

Q This has previously been marked as Plaintiff's Exhibit 96.

While you're looking at that, Ms. Lambridis, I'll just identify it for the jury. It purports to be a photocopy of an

e-mail from Anthony Castellazzo to a lot of people, including Mr. Bitler, Mr. Dowling, and ultimately copied to you. And the date on Plaintiff's Exhibit 96, the date of e-mail is November 14th, 2007.

Did you get that e-mail?

A Yes.

Q On the second paragraph, it says: "We all have plenty on our plates and we'll continue to for some time. That state of affairs is nothing new. Considering the recent push in production demand and having to provide enough resources to meet this immediate need, the needs of the Tech Transfer Project continue to suffer from insufficient resources." And then the paragraph goes on.

Do you know what Mr. Castellazzo is referring to when he talks about there being a recent push in production demand?

A I don't know specifically what he's referring to, but it usually means that there's been an increase in the need -- it could be any product. In other words, we have an increase in business or an increase in

orders.

Q This is about two months after you arrived, November 14th, 2007; correct?

A Correct.

Q Were you aware that there was a recent push in production demands in November 2007?

A The context of this memo is back to what I stated earlier. The Little Falls facility was significantly smaller than the Riverview facility. So part of the reason for the move was because we could obviously produce more in the bigger facility because we would have more production rooms and more equipment. So Tony Castellazzo is referring to the tech transfer, meaning activities surrounding getting the new building approved, and that our increasing demand for increased number of orders for product, that the sooner that we can do that, the better.

Q Okay.

A The sooner we move, the sooner we'll get to a point where we'll be able to meet this increase in demand. The recent push

means that it's the planning group and the sales and marketing group telling us we have an increase in orders, so we need to work toward getting the means to produce everything.

Q So there is an increase in orders and a concern that LF -- Little Falls; correct?

A Right.

Q -- Little Falls represents a finite production capacity, even though you're getting these sales orders; is that what you just meant?

A Yes.

Q So it was important in the fall of 2007 to have a way to produce more Digitek and other products; would you agree with that?

A Yes. And that's what the next sentence says.

Q And at the present time, meaning November 2007, there's sales orders coming in; there's a need to have more production; and there was concern that it wasn't happening at Little Falls and you needed a bigger place;

correct? That's what you just said?

A I think that's one way of looking at it, but there could also be a demand in business where you can't accept that business until you have more capacity. So --

Q Which would not be a good thing for the company?

A Right. You don't want to turn down business.

MR. PETTIT: And I notice that the sun is now sinking, and it's about to hit your face. So if you have a problem with that, please let me know. We'll do something about that.

All right. I'm finished with that document. So this will be 123.

(Plaintiff's Exhibit No. 123 was marked for identification.)

BY MR. PETTIT:

Q While you're taking a look at that, Ms. Lambridis, I'm going to just identify what it looks to be to the jury. It looks to be an e-mail from Rahana Hussain on behalf of Augustine Frimpong dated April 14th, 2008, to,

again, a lot of people, including Phyllis Lambridis. The subject is FDA Communication, and there's an attachment about digoxin tablets.

Did you receive that e-mail?

A Yes.

Q The attachment, at least the way it was produced to me, was a two-page letter, Actavis 001423940 to 941. Is that what it looks like to you, a two-page letter, and then there's an electronic signature page at the very end?

A Yes.

Q Does that attachment look like it goes with that e-mail?

A Yes.

Q Who is Jacob Haroon, Ph.D., who is the person FDA sent this letter to at Actavis?

A He was the director of regulatory affairs at the time.

Q The first sentence -- and you would agree with me this is a letter from the FDA to Actavis; correct?

A Yes.

Q On the second page, it's from Florence Fang of the FDA.

A Correct.

Q The first sentence of the letter: "Dear Sir: This refers to your supplemental new drug application dated January 22, 2008."

And then there's a reference to a regulation for digoxin tablets. Now, I paraphrased the sentence, but you would agree with me?

A Yes.

Q And it refers to -- at the middle of the page to Actavis Totowa, LLC, 900 Riverview Drive, Totowa, New Jersey; correct?

A Yes.

Q And the next paragraph makes a reference to a phone conversation on February 27th, 2008, between the FDA and Jacob Haroon, Ph.D., who's the head of regulatory at the time for your company?

A I'm sorry. I didn't hear the first part of your --

Q Sorry. I had a lot packed into it. That's why. Sorry.

Let me start: The letter states: "Reference is also made to the February 27, 2008, telephone conversation between Nitin Patel of this Administration "-- that's the FDA; right?

A Uh-huh.

Q -- "and Jacob Haroon and Augustine Frimpong of Actavis Totowa LLC." And the sentence goes on.

A Right.

Q And in the next sentence, the FDA says: "The change that you described is not, in our opinion, the kind permitted by regulation to be put into effect in advance of approval of the supplement."

Did I read that correctly?

A Yes.

Q Now, can you tell the jury, if you know -- and I know you're not in regulatory, so tell me if you don't know. I don't want you to guess.

Do you know, is this the FDA telling Actavis that they cannot produce Digitek in Riverview yet; something else has to happen?

A It's telling them that their supplement to move the manufacturing there can't proceed yet. But you have to make product in that facility to get it approved, so it doesn't prohibit them from making batches there.

The context of this letter is that there are different types of supplements to be filed for changes. The company chose the category as the changes being effected zero, meaning that it would be immediately effective.

Q Zero days?

A Zero days, meaning that once it was filed, it would be immediately effective. And upon doing so, they received this phone call from the Agency on the 27th stating that a GMP inspection would be required before they would grant it.

So this letter is just follow-up to that conversation. It sort of makes it official. But the facility at Riverview Drive was part of Actavis Totowa, the company Actavis Totowa.

And there were ongoing discussions with FDA prior that they considered that what they called a contiguous site. Because it was within a certain mile radius of the original facility and because it was part of the same company, they considered it, as I said before, a contiguous site, which means the level of work to be done in terms of filing and the approval process for making changes between those facilities is less burdensome.

So with that understanding, Actavis filed a change -- the changes being effected supplement. The Agency then came back on the 27th and clarified and said even though it's the same facility, we want to come in and see that building and do an inspection on that particular facility before you make the change. And that's what led to the inspection that occurred in March.

So this letter came at a later date, I believe.

Q That's actually my next question. So --

A Yeah, it came at a later date, but

that's just the Agency's very slow process.

Q The FDA letter -- I'm sorry.

A I'm sorry. I'm just saying the Agency is very slow sometimes. They reacted quickly with the phone call, but then the letter comes later because the letter is typically after a review.

Q Let me ask you a specific question about the date, and then we'll figure it out. There's an email that says April the 14th.

A Correct.

Q And that transmits this to a number of people. It's from Actavis to Actavis. It's an internal e-mail.

A Yes.

Q And that's April the 14th.

A Yes.

Q Now, we know this letter is at least after February 27th?

A Yes.

Q Can we narrow it down any more than that when this letter was received?

A Based on practice, it would have been received by the regulatory group that

distributes it either the same day or the day before. So they would --

Q Meaning April 13th or 14th?

A Automatically. If you go to the back on the electronic signatures, the electronic signatures show you April 7. So that's when FDA signed off on it. So it came through the US mail after that.

Q Now, do you know, without guessing, since you're not in regulatory, whether the FDA ever formally permitted Digitek to be produced at Riverview?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: In other words, were they ever approved to manufacture it there? Is that what you're asking?

BY MR. PETTIT:

Q Yes.

A No, because that -- not that I'm aware of.

Q Without guessing, is it necessary for the FDA to approve it to be manufactured at a different facility when the Little Falls

facility had been making it up until then?

A Yes. The FDA needs to approve or, by some of these other mechanisms, at least be notified of the change. If that facility had already had a GMP inspection, then they could have just moved it and notified FDA. They wouldn't have to wait. The waiting part had to do with the GMP inspection of the facility, not the product itself.

Q Okay. So do you know whether the FDA ever finally approved the production and manufacture of Digitek at Riverview?

A When I was there, as far as I know, no.

MR. PETTIT: All right. We're going to take a break because we're at the end of this tape. And I'm actually pretty close to being finished.

THE VIDEOGRAPHER: We are now going off the record. This is the end of Videotape No. 4. The time is 3:50.

(Short recess.)

THE VIDEOGRAPHER: We are now back on the record. This is the

beginning of Videotape No. 5. The time is 4:01.

BY MR. PETTIT:

Q I'm showing you what was marked as P-16 at an earlier deposition. And it's a large document. And there is handwriting at the top that says: 1 through 67. And if you look at the very last page, it says: 67 of 67. I'm stating this for the record. And it's already been marked and introduced into evidence at another deposition.

I want to show you some pages out of this document. And if you need to slow down and look at the page before or the page after, whatever, you have to tell me. Otherwise, I'm going to believe that you understood the question and were able to answer it.

Is that fair?

A That's fair.

Q Can you look at the Bates number at the bottom and go to 859? You know what, that's not even going to work.

Let's go off the record for a second.

THE VIDEOGRAPHER: Off the record, 4:03.

(Discussion off the record.)

THE VIDEOGRAPHER: Back on the record, 4:03.

BY MR. PETTIT:

Q Ms. Lambridis, I think an easier way to get through this document will be to look at some of the handwriting at the top, Page 2 of 67, 3 of 67, and so forth. All right?

A Okay.

Q Now, on Page 6 of 67, if you would turn to that, now, this is a page out of an Investigation Log No. 07-093.

Do you see that?

A Yes.

Q And do you recognize that as the number that we were talking about about a half hour ago as an investigation number which may have been about the batch that Mr. Bitler did the investigation?

A Yes.

Q And this is Mr. Bitler's signature; is that correct?

A Yes.

Q And it purports to have been signed -- and I know you don't know for sure, but at least the document purports to have been signed January 25th, '08; correct?

A Correct.

Q Now, the section that -- you're familiar with this form because it's a quality group form; correct?

A Yes.

Q And this is Section IV of the form. It says "QA & Regulatory Evaluation."

Correct?

A Yes.

Q Now, Mr. Bitler signed in that section, but he's not in regulatory, is he?

A Well, the section is for QA & Regulatory Evaluation.

Q Is there supposed to be a signature from anybody from regulatory?

A In that particular case, he's signing for QA. It says: "QA Review Investigation for Completeness and Accuracy and preventive actions for appropriateness."

Q I'd like you to turn to 59 of 67. I'll zoom out for a moment so the jury gets a sense of this page. And this is referring to an On-Line Product Inspection Form, or that's what it is; right?

A That's the title of the form, yes.

Q And it's dealing with Batch 70924A1. And that's, according to your testimony, one of the designations for this batch, always speaking about the same batch that Mr. Bitler investigated; right?

A Correct.

Q And at the bottom where it talks about Management Comment, it says that a total of 15 tablets with approximate double the thickness were removed during the inspection of this batch.

Did I read that correctly?

A Yes.

Q So it's your understanding that a total of 20 tablets were found; correct? Not on this document, but a total of 20 out of that batch; is that your understanding?

A Yes.

Q And is it your understanding that some were found in the production part of it or the packaging part of it -- I'm using those terms the wrong way.

It was found while -- in the normal course of business as the pills were going through; correct?

A Correct.

Q And then some pills were found during the investigation?

A Yes.

Q And according to this, 15 of the pills were found during the investigation; is that your understanding?

A According to this form, yes.

Q Do you have any other understanding other than that?

A No, I have no other detail.

Q Do you know where the 20 tablets are today, the 20 out-of-specification tablets that were found in Batch 70924A1?

MR. DEAN: Objection; asked and answered.

Go ahead.

THE WITNESS: I don't know where they are. They were not available during the time of the FDA inspection because the batch had been released, and they were subsequently rejected as we would during the normal course of business.

BY MR. PETTIT:

Q "Rejected" meaning they were not released?

A Correct.

Q And do you have an understanding that they were destroyed or lost or turned over to the lawyers or some other possible result?

A It was my understanding from the conversations during the inspection that they were no longer available because they were destroyed.

Q Who told you that they were destroyed?

A That was part of the conversation with Erin and Scott Talbot.

Q I'm sure this was asked and I

apologize, but when was that?

A During the time frame that I referred to earlier when she reviewed the investigation, beginning of April.

Q Turn over to the next page, please. That's Page 60 of 67. And the title of this page, at least, is Digoxin Tablets .125 milligrams, and, again, dealing with Lot 70924A1; correct?

A Yes.

Q And it's referring to something called a tightened AQL inspection; correct?

A Right.

Q Do you know what that is?

A Yes.

Q What is it, please?

A I can't recall what the letters "AQL" stand for. But what it is is it's a requirement -- whenever a batch is produced, QA will then do an inspection of that batch prior to its release. That inspection varies, depending on the product.

In this particular case, I would have to read this. If you give me a minute,

I'll take a look at it and I can speak in more detail.

Q Well, I want you to read it until you're comfortable, but I'm actually not going to ask you detailed questions.

I'm asking: What is an AQL inspection, in general?

A An AQL inspection is the inspection QA would do in order to make its decision to release. The tightened part of this is -- when you say it's tightened, it means that the criteria is stricter. So it would appear that this AQL inspection was done, again, after the work that was done to inspect the batch and pull those 15 tablets out. Then QA then went in and did a sampling of that batch to do further inspection before making the decision to release. So this part was done by various production people, not QA, where they found these 15 tablets. QA always comes in after the fact.

Q Where did you come to that conclusion?

A Based on the --

Q Let me ask a clear question.

When did you come to the conclusion -- what's the basis for your conclusion that the 15 out of the 20 tablets were discovered by people in production rather than people doing Investigation 07-093?

A I'm basing my answer on the signatures that I see here. But under normal circumstances, when an activity like this occurs, if it's not already proceduralized, it will be written out in some kind of protocol or document which QA approves.

Just because the inspection took place of the batch, QA would not inspect the batch and then do a review of the batch and release the batch. Someone else would have to do that inspection in order for QA to come in as a third-party review to release the batch.

So what I am seeing here is on this page, which is the inspection form, the results of the inspection, which these initials and signatures look to be either packaging or production people. It refers to a protocol that they follow. And then this

document --

Q What signatures? I don't mean to interrupt you, but I'm trying to keep up with your answer.

A On this Page 59, which was the prior page, if you look like where 1 is and it says "Done By, Date, Checked By," those are initials. And then it says -- and that's to clear the room to say you can take product into this room, it's clean, et cetera.

Q So you're giving a lot of testimony.

A I'm sorry.

Q I don't mean to interrupt you, but I'm trying to keep up.

A Do you want the detail or am I --

Q Well, I just want to stop you every once in a while. You can keep on going with your answer. I'm just trying to keep up.

Are these the initials you're referring to in your answer just then?

A Some of them, and the others are above.

Q So these initials here. And can you read any of them?

A I'm referring to the initials down in the box in the middle where it says "Done By" or "Checked By."

Q Oh, here?

A Right. Those are initials of individuals.

Q And do you recognize that -- and I apologize. I don't mean to talk over you.

Do you recognize those initials?

A I don't recognize them, which is why I'm saying they probably were not quality signatures.

Q I'm going to ask another question. And when I'm done asking you these interim questions, if you were in the middle of answering something --

A Okay.

Q Do you know who those initials are --

A No.

Q -- Checked By?

A No.

Q Do you know who these initials are at the bottom? One says "Production

Management" and an initial.

A Right.

MR. DEAN: It might help if you look at the copy you have instead of that.

THE WITNESS: It would be -- again, production management would have that signature, and then there would be a QA signature there, but that's an approval signature. It's not signing for the work done.

BY MR. PETTIT:

Q Whose initials am I highlighting here at the bottom of Page 59 of 67 if you can tell without guessing?

A I can't.

Q What is your -- I'm going to stop for a second. Do you remember if you were in the middle of answering some other question? It's really unfair. Just before I move on.

A I was explaining the tightened AQL.

Q Okay. I promise you I will come back to that when we're done. You had turned to this page, and I wanted to catch up with

you. I will get back to that page. Okay? Is that fair?

A Okay.

Q So on page 59 of 67, at the bottom it says "QA Approval," and there's some initials you don't recognize. And it looks like the date is January 18th, 2008.

Do you know, without guessing, what is the significance of somebody from QA signing their initials on that line?

MR. DEAN: Objection; asked and answered.

Go ahead.

THE WITNESS: Without seeing the actual protocol, I can't say what they're signing for. But it appears to me that it's typically verifying what's there. So QA usually is doing the second check on something.

So they do a verification -- someone does an action, and QA verifies it. So it's written there that there are 15 tablets, so QA most likely saw the tablets and verified that.

BY MR. PETTIT:

Q The date of the production management signature, initials, is the same as the QA approval; correct?

A Correct.

Q And then on --

A That would have to match for them to verify. Well, it could be a subsequent day, but typically they would be at the same time.

Q Would it physically be at the same time, same place, standing next to each other or does that vary?

A It can vary, depending on what activity is going on.

Q So you can't tell just from looking at this document whether the QA person, who we can't identify yet, did an investigation finding the 15 tablets or whether the production management did, but that's the normal policy; is that your testimony?

A The investigation is one piece. The inspection of the product is another piece. This refers to the inspection of the product.

And all I'm saying is that an

inspection was done. It appears to have been done by a production personnel where they found 15 tablets, and then QA came in and saw that it was 15 tablets and approved.

Q Okay. Now I want to go over to Page 60 of 67. It's the page we were just on a couple minutes ago. I'll zoom out again.

Now, at the bottom of this page is an approval by -- is that Ashesh Dave for packaging?

A Approved by, yes.

Q Can you recognize the signature?

A Ashesh, yes, uh-huh.

Q Is that how you pronounce his last name?

A I couldn't tell you.

Q And Dan Bitler is QA?

A Correct.

Q Now, is this one page that the jury's now looking at, which is Actavis 002615, other than the signatures and the dates at the bottom, which I'm going to put my hand over for a second, is the rest of it a preprinted form that could be used --

and, of course, the top where it says a number and a batch. Is the rest of that a preprinted form?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: No. It's written specific to this activity.

BY MR. PETTIT:

Q And it would be -- I'm really asking a poor question. Is the format that is used for referring to batches and holds and AQL sample, is that set forth in a form that people use? A template is a better way. That's what I should say.

Is there a template that people use to fill out an inspection like this, an investigation report like this?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: It varies from company to company, but there was --

BY MR. PETTIT:

Q Actavis.

A This is specifically a document

created to attach to the investigation. So it's not standard -- it's not a standard form.

MR. DEAN: "This" being Page 60 of 67?

THE WITNESS: Correct.

BY MR. PETTIT:

Q I want to ask you a question, and tell me if you're able to answer it.

A Before you do that, can I finish?

Q I thought you were. I apologize.

A As far as the AQL, if you look at this document, it gives you the history in the overview to say that two tablets were found. When they were found, they did a review of what was in front of them and found a total of five tablets.

It goes on to refer to the protocol that I mentioned a few minutes ago and indicates that this 100 percent inspection was done by the packaging department where 15 tablets were found. So that sort of brings you to those 20.

And the AQL, after all of that was done, QA went back and did what's called a

tightened AQL, which means that they then took what the packaging department deemed as the good product and did an inspection of those at that AQL level with that sample size. And it says there they inspected 1,250 more tablets; and the criteria was accept one, reject two for the batch.

Q Are you finished your answer?

A Yes.

Q The last bullet point, for lack of a better phrase, accept -- it says: "Accept on 1/Reject on 2 (total for batch)."

Does that mean that if one out-of-spec tablet -- one additional out-of-spec Digitek tablet is found, that the whole batch should be accepted; but if two additional Digitek tablets are out of spec or found, that batch should be not released?

A That's the criteria based on that AQL level. That's standard criteria. And it's based on the batch size and the sampling plan. So that's not pulled out of the air. That is criteria set forth by -- these are standards used by quality assurance

professionals in multiple industries, not just in pharmaceuticals.

Q There is the phrase "visual inspection" in some of these documents, "AQL," and "tightened AQL." For this particular investigation, 07-093, of this particular batch, can you tell me, was there a visual inspection, was there an AQL, and was there a tightened AQL? Were there all three?

A There was a visual inspection and a tightened AQL. There's typically a normal AQL for the release. But that was -- I don't -- I didn't review that, so I can't say for sure.

But that would typically happen at some point during the manufacture of the batch in order to get that batch through to the point where it would be packaged and released. So it may be in the regular batch documentation, which I don't have in front of me.

Q So now I'm not talking about this particular investigation, but there could be such a thing as a visual inspection and then an AQL and then a tightened AQL? Is that

possible, generally speaking?

MR. DEAN: On one batch; right?

MR. PETTIT: On one batch, yes.

THE WITNESS: Under normal circumstances, there's an AQL and the batch is released. Because this batch identified a problem -- in any batch that identifies a problem, it is possible that they would do a visual inspection and then another AQL before they release it.

BY MR. PETTIT:

Q So it is possible that you could have a visual and an AQL and a tightened AQL; that's possible?

A Yes, but not in that order.

Q What would the order be?

A It would be AQL, visual inspection, tightened AQL.

Q And the decision to have a tightened AQL would be made by whom, generally, at Actavis in 2007?

A It would typically be done by -- at Actavis it would be done by the director of QA, but it's standard practice. It should be

standard practice.

Q So I don't mean to be zigzagging; but back to this particular investigation, it's Mr. Bitler who would have made the decision to have a tightened AQL?

A Correct.

Q Do you know that from looking at the documents or it's just policy?

A It's just policy.

Q Do you know -- well, strike that.

Have you spoken to Mr. Bitler since you have left Actavis?

A No.

Q Did you speak to Mr. Bitler about the visual inspection which was currently part of 07-093?

A No.

Q Do you know from any other source, since you didn't speak to Mr. Bitler, how the visual inspection of 07-093 was conducted?

A I don't know the details, no.

Q You said a few minutes ago that the -- and I can put it back on the screen, but accept if one, reject if two, that bullet

point, you said that didn't come out of the clear, blue sky.

Can you tell me where it comes from?

A The AQL standards.

Q AQ -- is there something called an AQL sample plan?

A Yes.

Q Is that what you're talking about?

A Yes.

Q I don't want to put words in your mouth.

A Yes. But I will be honest with you; I don't have all the detail. I can't give you more than that to go on in terms of -- I can't give you a specific reference to where you can find them, but they're general standards used throughout industry. So it's a typical QA term.

Q Let me try to ask you direct, narrow questions if I can.

A Okay.

Q And you can tell me you know or you don't know. Is there something called an AQL sample plan at Actavis in 2007-2008?

A The sampling plans are based on AQL standards. So anything that's routine would typically be based on the AQL standards. This is nonroutine, so they would most likely have to go and research what the appropriate level of -- level should be for this activity for this particular scenario.

Q Appropriate level, meaning how much investigation?

A How many to inspect based on what the batch size is and what the sample sizes should be and how -- and then the sample sizes typically dictate what the criteria is.

Q Do you know, without guessing, where someone like Mr. Bitler would go to to check if this was a nonroutine situation?

A There are typical reference documents that QA would have on-site.

Q What are they called?

A AQL standards. There's books and published documents.

Q I want to go a step further back than that. Is there a standard which Actavis used to develop and define the AQL sample

plan?

A I think I just said that. It says here in this document: "The AQL sample will be pulled by QA based on the following." And they give you the level, the sample --

Q What page are you on, again?

A This is Page 60 of 67. It gives you the detail all here in those bullet points.

Q Okay. But I'm going a step further back than the AQL sample plan. Is there a standard that Actavis used to develop the AQL sample plan?

A No. The AQLs -- I don't know how to answer that. You go to this reference document. And based on -- for example, here it's saying your batch size is approximately 4,747 tablets. So, therefore, that dictates a certain sampling plan with a certain number of tablets.

And then you devise how you're going to randomly sample those. So you're using it as your guide. So you look at the reference -- you look at the AQL standards to determine the sampling plan. So they did that

and then -- the QA folks did that, and then they wrote down here what the criteria was and what they based everything on.

Q Let me try it this way: If there's a document called an AQL sample plan and if there's a document or a binder of documents called AQL standards, who writes them? Is it Actavis or is it something that comes to Actavis from an outside source?

A The AQL standards are from an outside source.

Q Where?

A I told you before, I don't know exactly where, but they're industry standards. And they're used in multiple industries, not just pharmaceutical.

Q Are they FDA approved, if you know without guessing?

A Absolutely.

Q And the ones that Actavis uses are FDA approved, if you know without guessing?

A They're accepted by -- it's accepted practice by FDA. They're not specifically approved by the Agency.

Q I'm not trying to jump on your every word, but I want to make sure the record's clear. So it's FDA accepted, not FDA approved?

A It's -- AQL standards are what FDA would expect you to use as a reference to develop sample plans.

Q How do you know that?

A Because when they inspect you, they typically want to know how you developed your sampling plans. And if you tell them you used the AQL standards, they're usually satisfied.

Q So if there is a standard that has been developed which was the source of the AQL standards, you don't know what that is; is that correct?

A I don't understand the question.

Q I'm trying to just find out -- I thought that you said, "I don't know," and I'm trying to make a clear record. If there is some source that was used by the developers of the AQL standards, you don't know what that ultimate source was; correct?

A It comes -- yeah, I do not.

MR. PETTIT: I think that's all I have. Can I have two minutes and I'll let you know?

MR. DEAN: Sure.

THE VIDEOGRAPHER: Off the record, 4:34.

(Short recess.)

THE VIDEOGRAPHER: Back on the record, 4:42.

MR. PETTIT: Ms. Lambridis, that's all the questions I have. Thank you very much. I appreciate it. And other counsel are going to have some questions for you.

BY MR. MILLER:

Q Mrs. Lambridis, my name is Pete Miller. We just met. The arrangement's that we're supposed to be done by 5 o'clock. I'm going to try to wrap this up as close to 5:45, which counsel has agreed to.

Your title -- correct me if I'm wrong -- vice president of quality and compliance; is that correct?

A US quality and compliance.

Q US for Actavis?
A Yes.
Q And the term "quality" in there, am I correct in saying that quality at a pharmaceutical department can be split into quality assurance and quality control?
A Yes.
Q And that "quality" in your title, is that QA and QC?
A Yes.
Q So a couple times during the deposition, you've referred to what you titled "QA folks at Actavis." Are you in charge of QA folks at Actavis?
A Yes.
Q And so I know we went through the AQL with great detail. I want to ask a couple follow-up questions. I'm not too much concerned about the AQL. But the final decision to accept if there's a lot with one tablet out of spec, reject if there's two; am I summarizing that correct?
MR. DEAN: Objection; misstates the testimony.

THE WITNESS: Can you just --
BY MR. MILLER:
Q Certainly. I can put it back up there if you like.
A No; just your question.
Q Certainly.
MR. DEAN: Go ahead. I'll just object again if I need to.
MR. MILLER: I didn't hear the objection the first time.
MR. DEAN: I think the first question misstated the evidence. I'm trying to find the exhibit now.
MR. MILLER: I don't know what my first question was.
MR. DEAN: It suggested that if one tablet in an entire lot was found wanting, you'd accept it; but if two were, you'd reject it. And I think that misstates what the exhibit says.
MR. MILLER: Well, I think I'm going to go with you on this. I think I'm going to put that exhibit back up on the screen.

MR. DEAN: I think it was a smaller number that related to that one and two, Pete. That's my point.

MR. MILLER: I got you.

BY MR. MILLER:

Q And that was Exhibit 16 previously marked. You had a copy of it, ma'am. It should be here.

A I put it back.

Q Okay. Fair enough. Specifically, I'm going to put that page in question back up you discussed at length.

MR. DEAN: Page 60.

BY MR. MILLER:

Q All right. We've talked at length about digoxin tablets. And this is a tightened AQL. And the bullet at the very bottom was we accept on 1 and reject on 2 (total for batch).

What is the -- as you understand it as the vice president of quality at Actavis, what is the "accept on 1" what? What is the 1?

A You are taking samples according to

the sample plan outlined above, in the bullets above. So you're going to inspect another 1,250 -- so they did this inspection, and they pulled the additional 15 tablets out.

And then from the batch, now that they were going to deem acceptable, they did a tightened AQL. So they took 1,250 tablets, 40 tablets from each of 33 drums, and then 10 tablets from the last drum, and they did -- QA did a visual inspection of them.

And the criteria based on the sampling plan was that it would be acceptable if there was 1 and they would reject based on the total batch.

Q Thank you. My question -- follow-up question would be: Does this tightened AQL carry on to subsequent batches and lots, or is this a one-time thing?

A The tightened AQL is typically done under these circumstances, and it's a one-time event.

Q And at the time that this was signed, we discussed January 2008, you were the vice president of quality and compliance;

correct?

A Correct.

Q And, well, my question is, then: Was there any criteria written up on how to handle the one tablet if one additional double-thick tablet was found?

A No.

Q Were you involved -- were you involved in discussions to determine that you were going to accept on 1 and reject on 2? When I say "you," I mean the company.

A I was not personally. That criteria comes out of the AQL standards.

Q Fair enough.

Have you had any discussions with any counsel in this case regarding potentially giving testimony at trial?

A (Witness shakes head.)

Q You indicated currently your status is consultant for Actavis?

A Yes.

Q How much are you currently getting paid by Actavis?

A About 12,700 per month. That's

before tax.

Q And it's not going -- is it going directly to you or is it going to your consulting company?

A It goes to the consulting company, and it's a two-year period.

Q During the entire time you were employed by Actavis before you became a consultant, you indicated that Scott Talbot reported to you?

A Yes.

Q Was his physical position, his desk, in Florida the entire time?

A His location was originally in Little Falls at the Main Street facility. And then he subsequently took a new role which placed him back down to Florida.

Q What were Scott Talbot's duties? What did his duties entail as far as the 483 inspection in 2008?

A During the inspection, he was on-site to assist. And he provided documents and interviews during that inspection. But because he was not actively in his -- he had

moved on to a different role at that point in time. So he was not full time on the site anymore, which is why I was the one that was the lead during that inspection.

Q What was the role that he moved into during the inspection?

A Well, it was before that. He transitioned into an opening that occurred in Florida. There was a director -- or actually it was an executive director of QA for that R&D facility -- our R&D facility in Florida. He left and took another job, and Scott applied for that role and wanted to move back down there because he was originally from that area.

Q Is it your belief that -- well, I'm correct in saying that you were the point person for Actavis during the inspection?

A Correct.

Q Is it your belief that Scott Talbot would have been the point person for the inspection had he remained here in Jersey?

A Correct.

Q And I believe you agreed to earlier

that there was a total failure of the quality department at Actavis during the inspection of 2008?

A It's a little out of context, but I believe the discussion was whether or not I agreed to it in a conversation with Erin during the closeout -- or during a meeting with Erin.

Q Did you, as the vice president of quality and compliance, during the FDA 483 in 2008 believe that there was a total failure of the quality control system at Actavis? And when I say that, I mean Little Falls and Totowa.

A We didn't present ourselves well to FDA, for sure. So it was very hard for me to disagree with Erin during our discussions because based on what she had reviewed, there were numerous issues that she was able to raise that, again, needed attention.

So, again, based on -- in the context of what we were talking about and based on the issues she presented, it was not -- it was something that I couldn't

refute.

Q Do you believe, as you sit here today, that if all the findings were presented in a different manner, that the production of 64 products would not have been discontinued?

A I don't understand the question.

Q Are you telling me that it was the way that the violations were presented or the inspection was presented that would have classified it as a total failure of QC?

A No. What I'm saying is that she reviewed a group of products that were known -- already known issues that -- and the reason that she focused on those is because we had already informed the Agency that we had a problem.

So when you're only looking at a problem, your conclusion -- her conclusion was then broadened to include everything. And her comments were based on a sampling of the many products that Actavis was making at the time.

Q So it's your belief that because she found issues with certain products, that it didn't carry over to other products?

A Say that again.

Q Well, you were indicating that Actavis stated that there were problems with certain products, and those were the products that they investigated?

A There's a mechanism and a requirement that if you have an issue -- if you do an investigation on a product that's been marketed, that you have an obligation to notify FDA.

So there were a number of -- and even without that, every FDA inspection, when they look at the quality system, it typically asks you for documents related to your investigations, your complaints, and so forth. And they use that as a gauge for what they're going to look at. So they come in, and she was looking at our investigation log and looking at investigations specifically. So obviously she was going to be looking at problem areas.

Q But you agree with me that it wasn't so much the investigation that led to the violations of GMP but how the investigations

were handled?

A Correct. She was not happy with how certain ones were handled. And how we got to it broadening beyond that was the fact that she focused on a certain number of products and then drew her conclusions based on that.

Q At the time of the inspection, Actavis was manufacturing 64 products; is that correct?

A I don't recall the number, but there was at least that.

Q Okay. And at least that and my list is including the Digitek. And my question is: You agree that 64 products, including Digitek, were discontinued because the quality control system at Actavis had several failures?

A I'm trying to find a short way to answer that. One thing led to another is the easiest way for me to say that. We talked earlier about PAREXEL's review and discussions that occurred with the Agency even prior to the inspection closing.

So Erin looked at a number of products that were subject to investigations

and was drawing conclusions and was asking us to prove to her that that wasn't the case with all products.

So that was why we had engaged PAREXEL. That was to get a third-party, unbiased review of these other products so that we could provide that evidence to the Agency to show them that the issue was not widespread.

Q But ultimately the FDA concluded that the issue was widespread?

A Based on Erin's comments, yes.

Q Based on the FDA inspector's comments?

A Right.

Q And did you find any fault with the FDA inspector's comments?

A I -- there were things that we did disagree on. But her comments were basically accurate, you know -- yes, her comments were accurate. What she presented was accurate.

Q As you sit here now, anything -- do you recall anything specifically that you disagreed with the FDA inspector as far as her

findings during the 483?

A Fundamental issues. I mean, Erin is a very good investigator, very thorough, but she has her own opinions, like anybody does. So she had feelings about things that we implemented that perhaps were given the go-ahead by prior FDA investigators that perhaps she felt differently about.

So there were things that were discussed during the course of the investigation that I viewed one way and she viewed another, but that's not unusual.

Q Can you think of any specifics, any issues or topics that she viewed one way and you viewed another?

MR. DEAN: I've been letting -- let me just object. I'll try to be succinct here. I've been letting the general inquiry about non-Digitek products go at a general level.

I don't object to her answering that question as to Digitek specifics. But as to general details -- I'm sorry -- as to specific details of discussions she

had with Erin about non-Digitek products, I'm going to instruct her not to answer the question as to details.

I might at a general level if you're inquiring about whether there was a concern about quality control; but as to the specifics, I'm going to instruct her not to answer on non-Digitek products.

BY MR. MILLER:

Q Were there any specifics that you recall that you disagreed on from the findings of the FDA inspector during the '08 483 inspection?

MR. DEAN: Let me just instruct you just to answer that with respect to Digitek.

BY MR. MILLER:

Q And I'll point out that you can answer with respect to Digitek or any general GMP violations. It can be general issues or Digitek. It doesn't have to be just Digitek.

MR. DEAN: At a general level, I'm fine. But if you're asking her for

specific comments about non-Digitek drugs, I think that is beyond the scope of what's in PTO-12 and 27. If you're at a general level, I'm okay with it. But I think your last question could lead her to go into specifics. And I'm just instructing her, as to specifics, to limit it to Digitek.

BY MR. MILLER:

Q If you understood all those instructions, ma'am, it's okay to answer.

A I think I can answer it. In the case of Digitek and with some of the other drugs that were recalled, I didn't always see the logic in extending it to all batches. And that doesn't mean that I didn't execute on all batches because there was -- when you're dealing in a situation as I was in, you get to a point where you just -- in order to advance to the next point and not belabor the point, there's certain concessions that are made.

So in the case of some of the other recalls, which based on his instruction, I'm not going to give you the detail, but there

were situations where there was an issue with one batch and, through her interpretation, it implicated all batches.

Q How many -- I'm sorry.

A And I didn't always agree with that.

Q How many of the 64 products, give or take -- I understand your position there -- were ultimately recalled?

A All the products were recalled.

Q And was that every batch in every product?

A Yes.

Q So --

A But there were multiple recalls, so you have to distinguish one from the other. There was a set of recalls that was done initially for stability-related issues. Those are the ones that I'm referring to now when I say that one batch with a problem, even though it was a stability batch, to me did not always mean or based on -- based on the issue -- again, I can't go into detail.

But her view was that it should have been all batches based on that, and my view

was that I didn't believe that was the case. But I didn't argue that point. I conceded that point, and we recalled everything.

The 65 products that you're referring to is part of the last recall. And that recall, again, was a concession to remove product from the market in order for Actavis to even have a discussion with the Agency about next steps and getting their site back into a position where they can manufacture product.

Q Okay. Sixty-five products was the last set?

A Was the last set.

Q How large were the other sets? I thought 65 was the total universe of products at Actavis, Little Falls, Totowa?

A I don't recall, but I don't think so. I think 65 was the last set.

Q And, in your mind, Digitek was one product that was recalled on its own set?

A Correct.

Q Okay. And then there was a -- was the stability recall, was that the group of 65

or was that a subset of the 65?

A The stability group was the first set of recalls around the same time frame as the digoxin recall. And I don't recall if -- I think it was about a dozen products.

Q Was there also an out-of-specification group, an OOS group?

A That's the stability group.

Q That's the stability. Okay. Am I correct in saying that if a manufacturing company of pharmaceutical products violates a CGMP, that it's viewed that the lab has violated that CGMP for all products?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: I don't understand the question.

BY MR. MILLER:

Q Have you seen -- I'm going to hand you what's been previously marked, if you bring up, Mike, a copy of Exhibit 82, which was the Complaint for permanent injunction.

Have you seen this document before?

A Yes.

Q And what was the occasion which you had an opportunity to read it?

MR. DEAN: Let me just instruct the witness she can answer questions at a general level about this document; but, again, given PTO 12 and 27, I don't want her to get into specific discussions of products other than Digitek. But she can answer your questions at a general level regarding this document.

Go ahead.

BY MR. MILLER:

Q Well, this document was filed, if you look at the last page, on November 14th, 2008. And you were in your position as vice president of quality and compliance at Actavis at that time; correct?

A No. I resigned on the 13th. This document was filed but not in this form.

This is the final consent decree? Is that what I'm looking at?

Q No, ma'am. This is the Complaint that led to the consent decree.

A Oh, this is the Complaint.

Q And on November 14, 2008, I believe you were still at Actavis; correct?

A Yes. I did see this document. I, though, obtained it on the Internet.

Q Did you -- were you in the position of vice president of quality and compliance when you downloaded this off the Internet?

A Technically, yes, but I was not on-site. I resigned on the 13th. This was filed on the 14th. And then on the 17th, it was my last day on-site.

Q Of December?

A No.

Q November?

A Of November.

Q I'm sorry. I wrote down that you worked for Actavis until December 1st of 2008.

A On the record, I was paid until December 1st as an employee.

Q Oh, okay.

A But I didn't actively work there after the 17th.

Q So right around the time you were resigning is when you read this document?

A Correct.

Q And you read it -- did you read the entire document?

A Then I did, yes.

MR. MILLER: If you would, Mike, go to Page 6, and if you would enlarge Paragraph 13.

BY MR. MILLER:

Q Paragraph 13 -- and this is filed by the Department of Justice -- states that compliance with CGMP requirements assures that drugs meet the requirements of the FDCA as to safety and have the identity, strength and meet the quality and purity characteristics that they purport or are represented to possess. Drugs not manufactured, processed, packed, or held in conformance with CGMP requirements are deemed adulterated as a matter of law, without any showing of actual defect. Regulations implementing the CGMP provisions are set forth at 21 CFR 210, 211.

Did I read that correctly?

A Yes.

Q Do you agree that the drugs being

manufactured at this time would be considered adulterated drugs?

MR. DEAN: Objection to form. Excuse me. What drugs are you asking about? I want to be more specific.

MR. MILLER: Drugs manufactured by Actavis at Little Falls and Totowa.

MR. DEAN: And your question is what?

BY MR. MILLER:

Q Would you have considered -- did you, as the vice president of quality and compliance, agree with the Department of Justice that the drugs manufactured were adulterated drugs?

MR. DEAN: Objection; calls for a legal conclusion.

Go ahead.

Go ahead.

THE WITNESS: Answer it?

I wouldn't agree that -- no, I don't agree with the Department of Justice. I believe that there were issues involved with certain batches with

certain products that may have violated GMP and may have had issues, but I don't agree that all the drugs manufactured.

BY MR. MILLER:

Q Were GMPs violated in the production of Digitek?

A Technically, no. They followed standard practices. They did an investigation. They did all the necessary things that they should have done.

I think it was a judgment call perhaps on the amount of scrutiny that they put that batch through after finding such an issue. And it's always easy to look at it in hindsight and think of 50 other things you should have done.

But there was nothing related to that -- the only thing that I can -- they followed procedures that were in place. There was a mechanism in place. It was not done randomly.

Q I understand your answer to go specifically to the double-thick pills.

A Correct.

Q And I'm more of a broader question. The production of Digitek, if one were to review the 483 and all the write-ups, you agree that there were other write-ups about digoxin and Digitek other than the double-thick pills?

A I don't recall. I thought the majority of what was there was related to the one batch, but I don't know. Without seeing that, I couldn't comment.

Q All right. We'll certainly cover that as well.

Mike, would you blow up Paragraph 12, please.

FDA's inspections establish that the drugs being manufactured and distributed by Defendants are adulterated within the meaning of 21 USC 351, Paragraph (a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with the GMP requirements for drugs.

So --

MR. DEAN: Let me just -- is that just -- you're reading the question, and you're going to ask if you read it right? Or do you have a question?

MR. MILLER: You cut me off before I even got a chance to ask a question, Dick.

MR. DEAN: Go ahead and ask your question.

BY MR. MILLER:

Q Did I read that correctly?

A Yes.

Q And it's your testimony here that you disagree with that, or do you agree with that paragraph?

MR. DEAN: Let me object and reiterate the objection I gave before and instruct her not to answer about details of other non-Digitek drugs. She can certainly answer about Digitek, and she can answer at a general level.

Go ahead.

THE WITNESS: To me, this

paragraph just states what FDA does. FDA inspections establish that. It doesn't speak specific to Actavis. It's just stating that.

BY MR. MILLER:

Q Well, you're not an attorney; correct?

A I'm not an attorney.

Q If you go to that first page, ma'am, this is a Complaint that the United States of America filed against Actavis Totowa and other defendants.

And enumerated Paragraph 12 is: "FDA's inspections establish that the drugs being manufactured and distributed by Defendants are adulterated."

It's not what the -- I'll represent to you that it's not what the FDA does. It's not explaining a duty. It's explaining a finding that if methods used or facilities or controls used for their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with the CGMP requirements for

drugs, what they've done is defined what an adulterated drug is.

Do you understand the paragraph, ma'am?

MR. DEAN: Same objection. She can answer with regard to Digitek.

I instruct you not to answer as to the specifics on other drugs.

Go ahead.

THE WITNESS: I'm sorry. Now that I'm rereading the paragraph, can you ask me the question again?

BY MR. MILLER:

Q Certainly. Do you feel that you understand the paragraph now?

A Now I understand the paragraph, yes.

Q Had you received training in CGMPs as a vice president of quality and compliance?

A Yes.

Q Are you familiar with US -- with 21 USC 351 (a)(2)(B)?

A Actually, not specifically. I couldn't tell you what that reference is in detail. GMPs are Sections 210 and 211 cited

below.

Q But you're not familiar with Section 351?

A I may be, but I can't recall what section that is.

(Plaintiff's Exhibit No. 124 was marked for identification.)

BY MR. MILLER:

Q I'm going to hand you what I'm going to mark as Exhibit 124. Ma'am, this is, I'll represent to you, Title 21 of the Food and Drug's Chapter 9, Subchapter V, Part A. And specifically it's Section 351 titled "Adulterated drugs and devices."

And the only section that's specifically cited here in the Complaint by the United States is 351(a)(2)(B). And that is: A drug or device shall be deemed to be adulterated -- and it goes into (a)(2)(B) here -- and that is poisonous, insanitary, et cetera, ingredients; adequate controls in manufacture. And (2)(b) goes on to say that it is such if it is a drug and the methods used in, or facilities or controls used for,

its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to assure that the drug meets the requirements of this chapter as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess.

A, did I read that correctly?

A Yes.

Q Have you seen this document before?

A No.

Q Did you receive any training on the topic when you received training on CGMPs?

A I've read this in the context -- elsewhere but not in this specific section of -- this description is in other parts of GMP but not in this -- I've never seen this section.

Q Okay. Do you agree that if a pharmaceutical lab for a manufacturing company has issues with manufacturing, processing, packing, or the facilities or controls used

for, that that labels the drugs manufactured by that company as adulterated drugs?

MR. DEAN: Calls for a legal conclusion.

Go ahead.

THE WITNESS: I don't know where the lab fits into all of this. You keep referring to the lab.

BY MR. MILLER:

Q If the QC, quality control, systems of a pharmaceutical company are in violation of Section 351, Adulterated drugs and devices, is it -- would you agree with the statement that if there is a processing issue or something wrong with methods used in the facilities or controls, that it's deemed that the adulterated drug extends out to all products made?

MR. DEAN: Same objection; calls for a conclusion of law, also assumes facts not in evidence.

Go ahead.

BY MR. MILLER:

Q It's okay to answer.

A It's a very convoluted question, but I'll try to answer it.

I think what you're asking me is that if a company is in violation of GMP or if something is not produced under GMP conditions, is it adulterated?

Q Yes. You asked it much better than I.

A Yes.

Q You agree with that?

A It is.

Q And you agree that if Product A is the one that has the CGMP violation for manufacturing processes or whatever issues, if Product A uses the same manufacturing process and issues, that it is also an adulterated drug? Is that what the --

A No.

Q -- Complaint is stating?

MR. DEAN: Objection to form; calls for a legal conclusion.

THE WITNESS: No, I don't agree with that because you're talking about a process. And to me, a process that you

use to manufacture is how you manufacture that drug.

And there's a formulation that's associated with a certain drug. And not all drugs are produced with the same formulation or the same process.

BY MR. MILLER:

Q You would disagree with the statement that if a quality control system department of a pharmaceutical lab had a GMP violation in stability, that that general GMP violation doesn't carry over to stability for all products?

A Still, it's not -- it would depend on the case. You're -- you can have a stability issue or a problem with -- it would vary -- you'd have to be more detailed to that.

Q As we sit here, you're not aware of any GMP violations on Digitek in particular?

A No, I'm not aware of any on Digitek in particular.

Q Let's go to Page 7 of the Complaint, Paragraph 16.

Blow that up, please.

Paragraph 16 states that the FDA's inspection of Actavis Totowa's Little Falls facility from January 10 to February 8, 2006, revealed that the firm failed to comply with GMP requirements in several respects, including, for example, it failed to investigate unexplained out-of-specification testing results for drugs, specifically 21 CFR 211.192.

And my question is: Do you agree that failing to investigate unexplained out-of-specification testing is a violation of CGMP?

MR. DEAN: Objection; calls for a legal conclusion.

Go ahead.

THE WITNESS: Yes, it is a violation.

BY MR. MILLER:

Q If we go to Page 10 and take a look at Paragraph 21, the Complaint by the US Department of Justice goes on to say that from March 18 to May 20th, 2008, FDA inspected

Actavis Totowa's Riverview Drive facility. Throughout the inspection, the FDA investigators advised defendants of the numerous and significant deviations from the CGMP requirements that the investigators observed so the firm could take responsive actions to protect the public health.

Ma'am, you would agree that you were part of the conversations in which the FDA investigators advised Actavis of the numerous and significant deviations from CGMP?

A Yes.

Q And do you agree that there were numerous and significant deviations from CGMP during the March 18th to May 20, 2008, inspection?

A Yes, I would have to agree.

MR. MILLER: Would you call up Exhibit 91.

BY MR. MILLER:

Q That first page -- we've gone over this document in some detail. I'm going to make a very good attempt not to ask questions that have already been asked, although I'm

going to cover some statements that have already been covered.

MR. MILLER: If you would enlarge the summary of the establishment inspection report that was discussed earlier.

THE WITNESS: Could I have a copy?

BY MR. MILLER:

Q You certainly may.

That summary was already read into the record earlier, but I'll read the first sentence again: An inspection of this large generic prescription pharmaceutical manufacturer was conducted as a qualifying GMP inspection of a new site, 990 Riverview Drive, Totowa, as per FACTS Assignment -- and it gives the number, Operation ID, number.

When it states that it's an inspection to qualify the GMP department, am I paraphrasing that right?

A There's no GMP department. It's doing a general GMP inspection of a site.

Q And when you use the term "general

GMP inspection," would they look at good manufacturing practices -- if they look at, say, stability and the amount of time that you have in this field, will they go through and qualify GMP stability for every product or do they qualify stability for one or two products? They wouldn't go through 64 products? -- is my question.

A Correct.

Q So there's a general term there where, okay, three or four products or whatever number it might be are approved for GMP for stability, or any other example, then it's approved across the board; is that correct?

A They look at the system itself, and they use a sampling of the products to determine if that system's working.

Q Would you agree with me that when they look at the system, again, they look at stability; they don't look at stability for each and every of the 64 products; is that correct?

A Correct.

Q And does the counterpart hold true? When they come in to inspect, they won't inspect every product's stability testing; they'll inspect a couple and then say you violated the GMP for stability across the board; is that correct?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: If it's not specific to a product, yes, then that would be true. So if they found a problem that was related specifically to one product, then you couldn't make that assumption. But if they found a general problem, then you could.

BY MR. MILLER:

Q Would you describe a general problem? If they found GMP violations in three or four products out of 64, that then does it become a general problem?

MR. DEAN: Objection; incomplete hypothetical.

BY MR. MILLER:

Q It's okay to answer.

A I was just saying that that's just not the best example to use for that.

Q You're in the field. Give me an example.

A Say what you were -- what you asked.

Q Well, we've identified if one product is tested for something, say, stability, and that one product is the only product that's been found to violate CGMP, that we consider it a one-product problem.

In your mind, if there's 65 products, how many products have to fail stability before you would say it's a general GMP violation?

MR. DEAN: Objection; incomplete hypothetical.

Go ahead.

THE WITNESS: Their inspectional approach is to look at systems. So there's six systems. So stability is part of a laboratory system. So when they do an inspection, they typically look at a quality system. And even in the quality system, there are a

lot of subcategories based on the different activities that quality performs.

So when FDA's review -- they need to review enough to make a -- to draw some kind of opinion of what -- whether they feel that that system's working or not.

And what you're -- where you were going with that is that if they find one thing wrong, they're not going to necessarily implicate the whole system; but if they find multiple things wrong, then they would implicate the whole system.

BY MR. MILLER:

Q Yes. And my question is: Being that you've been in the field for so many years and have so much experience, how many multiple -- and by way of example, the laboratory system, stability testing, what is your opinion as to how many products would have to fail or issues in stability, violations of CGMP would they have to find

before it is an across-the-board, general problem?

MR. DEAN: Objection to form; vague, ambiguous; lab system's undefined, numerous other terms undefined. The question is vague and ambiguous.

BY MR. MILLER:

Q It's okay to answer.

MR. DEAN: Go ahead if you can.

THE WITNESS: I forgot the question.

BY MR. MILLER:

Q Using your term, "laboratory system," stability testing falls under laboratory systems, which we have established. And you indicated that one would be a problem with that product, and you also indicated that "multiple" would be an indication of across-the-board problem.

My question is: How many?

A How many? There's no definitive number.

And just to clarify, in this particular case, we had multiple stability

failures that led to recalls and those products were recalled; but they were product-related because, generally speaking, the lab got a clean bill of health in this inspection, for the most part. That was the area that they praised in terms of labs. So the fact that the lab found the out-of-specs, I mean, it went to their credit.

If you recall, you put something up a few minutes ago that criticized the company from the prior inspection, whereby they were not opening any investigations. And you asked me if that was a violation of GMP, and it is.

So the company had come quite a ways in that they were opening these investigations. Now, of course, they were now cited for failing to close them in a timely fashion, but it was a new problem. It was a related problem.

But now the company was -- the laboratory was actually given kudos for the fact that it had done well during this inspection, despite the stability failures because they were product-related. They were

related to either an issue with a product or a batch or a method or something, something else.

MR. MILLER: Let's go to Page 2 of 95. And blow up the last five lines. There's a sentence that begins with "however."

BY MR. MILLER:

Q And if you could start, read whatever you need to catch up. But it begins with "However," the bottom of the page, four or five lines up from the bottom.

And it says regarding this inspection: However, there is no assurance of the strength, quality and purity of the approximately -- redacted number -- of other products that remain on the market, all lots remaining in the two distribution centers, and the in-process products that remain at the firm's Little Falls, New Jersey, and Totowa, New Jersey, locations. The products were manufactured, tested and released by the same quality system.

Now, do you find praise in that --

MR. DEAN: Objection. She said that the lab was given high marks.

THE WITNESS: The laboratory.

BY MR. MILLER:

Q Does the laboratory do the testing that assures strength, quality, and purity?

A The laboratory does the testing, but QA releases the product. And from what we've seen throughout, the QA group is the group that was targeted here, not the lab.

Q Can you think of any document that gave praise to the lab as you sit here? Is there any document that stands out in your mind?

A There should -- I don't know if we had it in front of us today, but there's references to conversations about the laboratory in some of the documents related to this inspection. So it should be in the minutes somewhere, perhaps the closeout minutes. I don't recall where we saw that.

MR. MILLER: We're going to take a quick break to swap out tapes. Let's make it real fast, like five

minutes, so I can wrap this up.

THE VIDEOGRAPHER: We're now going off the record. This is the end of Videotape No. 5. The time is 5:32.

(Short recess.)

THE VIDEOGRAPHER: We are now back on the record. This is the beginning of Videotape No. 6. The time is 5:38.

MR. MILLER: Mike, Page 13 and blow up the paragraph that's titled "Inspectional Coverage."

BY MR. MILLER:

Q If you take a look at that, please, Ms. Lambridis. Under Inspectional Coverage, it states: "The inspection was planned as a qualifying cGMP inspection of the new site "-- redaction -- "and preapproval inspection. Due to the cGMP issues identified, the Quality System was the only system reviewed. The inspection did not include the review of preapproval applications. However, a list of pending ANDAs and supplements was provided as Exhibit 25."

The next sentence: Although a review of the new laboratory was conducted, comprehensive coverage was not afforded due to the significant deficiencies of the Quality System.

Do you recall that due to the deficiencies, significant deficiencies of the quality system, that there was not comprehensive coverage of the laboratory? Do you agree with that statement?

A They did not do a full laboratory inspection. As I explained before, there are six systems. Quality is one, packaging is one, manufacturing is one, laboratory is one. So they looked at the quality system only. And as I said, under quality, there's subparts that interact with the lab, so investigation, complaints, things that are related to laboratory testing. So they didn't do -- this is correct in that they did not do a comprehensive review of the laboratory.

Q Okay. So when they say "quality systems," what different departments fall under that?

A Mainly QA, but it relates to other -- it relates to all areas. That's why they look at the quality system because it relates to the entire facility. So it involves change control, annual product reviews, investigations, complaint handling, things that would go across the board.

Q But you agree that due to the significant deficiencies of the quality system, that comprehensive coverage of the laboratory was not conducted? Do you agree with the statement?

MR. DEAN: It doesn't say "comprehensive coverage of the laboratory." You added a word there.

THE WITNESS: It says here they did review the new laboratory. So there was an inspection -- part of this inspection included a review of the laboratory at Riverview, but they didn't do the full laboratory GMP inspection.

BY MR. MILLER:

Q But the plan was to do just that?

A The plan was to do a GMP inspection

and a preapproval of the entire facility.

Q But you agree that due to significant deficiencies in the CGMP area, that they never got to the second stage; correct?

A Oh, yes. That's what she's saying; they never got there.

Q Go to Page 15 of 95, please.

You agree that that quality system or the area in which there were deficiencies of the GCMP program were found, that Digitek was one of the products that fell under the umbrella of the quality system?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: What's that question again?

BY MR. MILLER:

Q Well, was it the significant deficiencies, violations of CGMPs that were found that ultimately resulted in the ceasing of production of all products at Actavis Totowa?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: You asked something specific to digoxin.

MR. DEAN: He changed the question.

MR. MILLER: I did because I forgot the first one. You're going to get me to forget the second one if you don't give me an answer.

MR. DEAN: Why don't you try again.

BY MR. MILLER:

Q As the vice president of quality and compliance at Actavis for a large area but speaking to Totowa and all the products that manufacturing of was ceased, were all the products terminated because of violations of GMPs?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: When we ceased manufacturing? You're referring to the cease of manufacturing?

BY MR. MILLER:

Q Yes.

A The products -- we discontinued manufacturing because Erin raised the concern regarding the fact that she couldn't -- she reviewed certain products and she had issues. And she extended that across the board and asked us to provide her with evidence to the contrary.

So in the absence of being able to present her now with evidence for every product, that it was -- that a review had been done and that it was good, we ceased manufacturing. And that's when we called PAREXEL in to do that review so that we could provide that to her.

Q And whether or not double-thick tablets were found in Digitek, production would have ceased on Digitek just the same?

MR. DEAN: Objection; misstates the prior testimony.

Go ahead.

MR. MILLER: I'm not stating any prior testimony.

BY MR. MILLER:

Q My question is: If double-thick tablets had never been discovered in any Digitek lot or batch, would you agree that production line would have stopped just the same?

A It would have been part of that group of products. Whatever we were manufacturing was stopped. So Digitek -- even if she never found an issue with Digitek, that's what you're asking?

Q Yes.

A If she never found any issue with Digitek, that would have been stopped with all the others.

Q No. I'm talking about that specific issue. There were several issues. I guess that specific issue of double-thick tablets, had that not been found, the production of Digitek still would have ceased?

A Yes, because we ceased everything. So it would have been included in the whole group.

Q And the whole group ceased because

of significant GMP violations?

A She found CGMP violations with respect to certain things that she had looked at and extended it across the board. And it was up to -- she was asking us to prove otherwise. So we had to stop in order to evaluate and provide that information.

Q And her findings came in the way of observations in the 483?

A Yes.

Q And it was those observations in the 483 and violations of the GMP written in that document that led to the cease of production of all products; you agree with that?

A Yes, even though we ceased before actually having the official 483.

Q Page 43 of 95, please.

And you agree that one group of production recalls were due to stability, but you agree that that was also -- included out-of-specification results; is that correct?

MR. DEAN: Can I have that question again? I'm sorry.

MR. MILLER: Well, yeah, I

agree. I think I lost myself on that one.

BY MR. MILLER:

Q We broke this recall in --

MR. DEAN: You're on Page 43?

MR. MILLER: I am. Yes, I am.

BY MR. MILLER:

Q We broke the recall down into separate groups, and it was Digitek on its own and then another group were stability issues and then another larger group of shutting everything down?

A Yes.

Q You agree?

A Agree. I think there was actually another group but --

Q Okay. There was another group on top of that.

A Another group.

Q Take a look at Observation No. 4 if you would, please. And I'm going to ask you a question about that, what's on the remainder of Page 43 after Observation 4.

A Okay.

Q I just want to ask you basically a general question without getting too much into the specifics.

You agree that this is a GMP violation found by the FDA specifically regarding Digitek, and it has nothing to do with the double-thick lot?

MR. DEAN: That Observation 4?

MR. MILLER: Yes.

MR. DEAN: Okay. Go ahead.

THE WITNESS: She -- it's -- part of this is the observation, and part of it is her background information. So the first sentence is the GMP -- the GMP issue. The "specifically" part is the example which involves Digitek.

BY MR. MILLER:

Q Right. It's an example of a violation of GMP; do you agree?

A It's the example she's using to state that that GMP issue was --

Q Was violated.

A -- violated.

MR. DEAN: Was observed. It's

an EIR.

THE WITNESS: Because she justifies her reaction.

MR. MILLER: Well, I'm not looking for your answer. I'm looking for her answer.

MR. DEAN: I'll clear it up later on. Keep going.

BY MR. MILLER:

Q Do you agree that specifically -- when you look at the paragraph "Specifically" and it says: Although three out of -- although three out-of-specification results were obtained for blend uniformity at the Right-Top sample location for digoxin tablets -- and it goes on and on. You've read it.

You agree that this is an example of a GMP violation that she recorded during her observation during the 483 inspection?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: She -- her observation is the first sentence. And

she's using what she observed with this digoxin to substantiate that GMP issue.

BY MR. MILLER:

Q And the GMP issue is she's outlining a violation of the GMP issue?

A Right. And then the rest of it is her rationale.

Q I'm sorry. We stepped on each other. Just to get something clean, her write-up is about a violation of a GMP specific to Digitek?

MR. DEAN: Objection to form. Go ahead.

THE WITNESS: No. That's why I'm saying it's not specific to Digitek.

BY MR. MILLER:

Q What is it specific to?

A She's using this digoxin example -- this example, which happens to be digoxin, to substantiate her claim that determinations of conformance to appropriate written specifications for acceptance are deficient for in-process materials. That's the GMP issue. She's using this as the example. It

happens to be Digitek. So it's not specific to Digitek is what I'm saying.

Q Even though it says "specifically" and gives an example?

A It says "specifically" to say because every --

Q I'm with you. Okay.

A Every observation has to be substantiated.

Q Okay. So is it specific to the GMP or the quality systems? It's specific to the quality system, not so much for Digitek?

A Correct.

Q And you agree that Digitek is one of the drugs being inspected by that quality system, so in that way it does affect Digitek?

A She's investigating the quality systems for the manufacturing facility that produces Digitek.

Q Right. And she has identified a violation of a GMP. And the example that she used to show that the GMP was violated --

A Was Digitek.

Q -- was Digitek?

A Correct.

Q If it was some other product that they make, even if they had said by way of example oxycodone hydrochloride tablets and that was the example, it wouldn't matter because the violation is a general violation that's outlined at the top; right? So it wouldn't have mattered to you --

A She's pointing out, yeah, what she observed to be a violation.

Q I understand. And if you take a look at Page 45 of 95, now, this issue, this out-of-specification issue goes to -- am I correct in using the term "blend uniformity"?

A In the last example?

Q Yes.

A Yes.

Q And blend uniformity is where you're testing to see if the amount of active pharmaceutical ingredient has dispersed evenly in the mixture; is that a good way to put it?

A That's a good way to put it.

Q And "out of specification" means that a sample that they took did not have the

proper amount of active pharmaceutical ingredient?

A It could mean that, but there are a lot of -- there's a lot of debate about the sampling technique playing a role in whether you get an accurate result.

Q But as a manufacturer of a product and vice president of quality, you do have limits set high and low of how much active pharmaceutical ingredient can be in a blend uniformity test?

A It has to meet the criteria for the finished dose.

Q Right. And in this example, it was Digitek that did not have the right amount of digoxin in the test sample; is that correct?

A If I can just look at this one more time.

Q Certainly.

A I don't know all the details here, but -- it's hard to do this with the redacted version. What was the question again?

Q Certainly. It discusses a Right-Top sample. You saw that?

A Right.

Q And there are several samples from different spots in the mixture. In this case, it was Digitek you're sampling; correct?

A Right.

Q And your department would look to see if the blend uniformity is correct; is that right?

A Correct.

Q And the blend uniformity, the out of specification that you're looking for is the percentage of the active ingredient digoxin in the mixture of Digitek; is that correct?

A You're -- the purpose of the blend uniformity test is to determine if the active ingredient is uniform throughout the batch.

Q And there's a high and low set on that to determine if it's outside?

A There's a range, uh-huh, yes.

Q And there were out-of-range or out-of-specification findings in these batches?

A The one location was out of specification, but you don't stop there. You

would have to look into whether that was -- what that was caused by because it could be analytical. It could be due to the sampling. It could be due to a number of different things.

She's indicating that a manufacturing investigation was not conducted, but something obviously was done because there was additional testing done. So without everything in front of me, I couldn't really -- I don't know the detail as to why they did additional testing and what the outcome of the testing is because all of this is redacted.

Q But you agree with the statement that in the finding, in the original findings in the lab, there was an improper amount of digoxin found in the uniformity of blend tests for those three lots?

A The analytical result was out of spec; but until you do an investigation and know what happened, you can't definitively say that it's a real result --

Q I understand.

A -- it's a valid result.

Q But ultimately you'd agree that the CGMP violation that the FDA inspector found to summarize all this was determinations of conformance to appropriate written specifications for acceptance are deficient for in-process materials?

MR. DEAN: Object to the form as to "found."

Go ahead.

THE WITNESS: Her concern here was that this issue didn't extend to looking at the manufacturing process. She's criticizing the fact that a manufacturing investigation wasn't conducted in this instance and that -- but it appears, in looking at the rest of this, that there were -- there was some type of investigation related to the laboratory and additional samples were tested.

BY MR. MILLER:

Q Would you --

A As I said, unless I read this whole

thing and have the investigation in front of me, I can't --

Q But you would agree with me that if she --

MR. DEAN: Wait. Let her finish.

MR. MILLER: Oh, I'm sorry. I thought you were.

THE WITNESS: I was going to say I can't give you more detail.

BY MR. MILLER:

Q Right. Okay. Well, you would agree with this general statement, that if she found that issue to be in compliance, she would never have written Observation 4? Obviously, she found a violation of a GMP or she wouldn't have found the observation?

A The intent of both the 483 and this report is to report what she observed to be in violation. She's stating what she thinks is a violation and why she thinks it is.

Q And that's what she's done here?

A And that's what she's done here.

Q Fair enough. If we go to Page 45 of

95 and blow up that very last sentence at the bottom, it says: "During the inspection, we were provided with a list of products that have been temporarily discontinued. The list includes 'blend uniformity issues' as a reason for the temporary discontinuation in the production of" -- and it goes on to list several drugs.

Does this represent the cease of production under the title of stability issues that you discussed?

A No.

Q No?

A Blend uniformity issues are not stability issues.

Q So this is above and beyond the stability issues --

A This --

Q -- or separate and apart from?

A Without looking at the exhibit that she's referencing here, I believe this list -- we presented several lists during the course of the inspection. But I believe this list was part of the product rationalization that

was referred to in some of the earlier discussions.

And at that point in time, there were those stop-and-fix-type products; and so there was reasons given for why certain things were discontinued. And in this case, she's just pointing out that these products were temporarily discontinued because of blend uniformity issues.

Q As the vice president of quality and compliance, you agree with the statement that digoxin would have been on the stop-and-fix list for out-of-specification violations had it not been for the Class I recall that was already in place?

A Absolutely, definitively no.

Q Why?

A Because there was not a repetitive issue with blend uniformity for digoxin that I -- other than that one observation that I knew of.

These products here had on-and-off issues related to some of the testing that were more -- there were more documented issues

regarding this.

And there were actually -- in the case of -- and actually in all three cases, we had ceased these products independent of the FDA inspection and were working on reformulating and working with -- in the case of the Chlor-Trimeton and the Drixoral, those were products we manufactured for Schering-Plough. And we had even their folks on board with trying to work on what were some of those issues. So we were --

Q When you say "issues," are you talking about some of the GMP violations that pertain to those specific --

A No, no. Blend uniformity. Blend uniformity we're talking about here.

MR. DEAN: Excuse me. It's about 6 o'clock. Are you about finished?

MR. MILLER: I can do it in 15 minutes.

MR. DEAN: Keep going.

BY MR. MILLER:

Q Look at Observation 5. Let's go to Page 48 of 95.

And it states: "Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality, and purity."

Is that a violation of CGMPs as written?

A You do know that this text is pre-written text. It's text that FDA uses to formulate their observations. So that is correct as stated, but it's the example, the "specifically" part, that she -- is her observation.

Q Right. But you discussed earlier that the observation is specific to a drug, but the GMP violation --

A No.

Q -- is general.

A No. This is a general -- when FDA does an inspection, if they see something that they believe is not conforming to GMP, they

take that example; and then when they write the 483, they have to point to a regulation that they think it's violating.

Q And she's pointing here to the --

A This is the regulation that she believes is being violated.

Q Right.

A But I'm just pointing out that that as written is a standard language that you'll find over and over again in a lot of 483s.

Q Right, because --

A To make it easier for the investigators, FDA has given them little blurbs that they use.

Q A boilerplate?

A Right. A template, yes.

Q A template. If you violate this GMP, bam, this template gets on there?

A Yeah, but they don't always synch up. I think this one's actually a very good example.

Q During the inspection, do you agree that she wrote up Actavis, the quality systems department, for this GMP violation? I don't

want to have to read it again, but do you agree that this is a finding of the FDA and this finding is a violation of GMP?

MR. DEAN: Objection to form. It's not a finding of the FDA.

THE WITNESS: I actually -- this is one that I disagree with.

BY MR. MILLER:

Q Okay. I'm not asking if you agree with it or not.

Is this observation a finding of the FDA?

A It's a finding of the FDA investigator, yes.

Q And do you agree that this finding as written is a violation of GMP? I'm not asking if you agree with it or not. I'm asking if it's, as written, a violation of GMP.

A I think it's an interpretation issue. I don't agree that it's a violation of GMP. I'll explain why if you'd like me to.

Q Sure, go ahead.

A The laboratory was in the Little

Falls facility. And the same people and equipment and methods were taken and they were moved across the road into the Totowa facility. And as a matter of an exercise, they used two analytical techniques to show that nothing changed when they moved as opposed to transferring everything and doing a re-qualification of every test method after it moved.

So, in other words, they took all the equipment and they re-qualified the equipment; but now they took the people and the methods, and there's something called a method transfer. Rather than doing that for every single method, they took examples and did a few. And it's her opinion that that wasn't enough.

Q In your mind, as the vice president of quality and compliance at Actavis, you think it's fine to take the general method, carry it 2 miles to the new lab, and produce multiple products even though you don't have the methods for each one?

A We're talking about test methods at

an analytical lab.

Q Right. Yes. Did I state that correctly?

A I just want to be clear that we're not talking about new product. We're talking about the testing of it.

Q Right.

A So the equipment was moved; so you would need to do work to show that when you move the equipment, it still works. That was all done.

If you had different people there, then I would say you need to do it one by one because now you have new people executing on the other end that you would want to make sure can follow the same method and have the same technique, et cetera.

But this was literally the same people going across the street and testing it. So we didn't do it in every case. We only did a small subset of it to show that it was good. And, in her opinion, it wasn't enough.

Q And by way of example, a specific method on how to do a particular test for a

particular drug would not have been on-site; it would have been at the other facility?

A No. It goes -- it's a method. It's written. You follow -- you look at the method and you test it here, or you go down there and you follow it there.

Q I'm lost. What was not on-site? What was it that the FDA felt like needed to be there and you didn't think it needed to be there?

A That you would go through an exercise with a protocol whereby you would test it here, the same batch, test it here and then test it there and show that the results are the same and -- it's a qualification. It's called test method transfer.

There's -- it's a standard practice, but you would typically do that when you're transferring it to another site where it's a totally different site with different people, different equipment, maybe not even your own site; it's a contract site.

So in this particular case, it was the same people and the same equipment that

just moved across the road onto the other side of the highway.

Q And you agree that the FDA felt that was a violation, but you did not?

A To me, it's a matter of an opinion here that it wasn't enough. It's not that we did nothing. It's that what we did they didn't believe to be enough.

MR. MILLER: I am going to wrap this up. I don't know if this has been marked as an exhibit or not, but just in case I'm going to mark it 125.

MR. DEAN: What is it?

MR. MILLER: It is the Mylan quality incident report.

(Plaintiff's Exhibit No. 125 was marked for identification.)

BY MR. MILLER:

Q Ma'am, I'm going to hand you what's been marked Exhibit 125. And it was a document produced by Mylan, specifically Mylan 0016459. And I will assume you probably haven't seen this in the past, but I'll ask you: Have you seen this in the past?

A No, I have not.

Q Well, it appears to be a report -- a reporter contact information. It's third-party supplier name, it's Actavis. And if you read through it, I'll represent to you it's contact information where Mike Adams talked to someone at Actavis.

And it's not real long. If you take a minute to read, I'd greatly appreciate it.

When you're ready for a question --

A I'm ready.

Q It's prepared on 4/23/08, at least it appears to be. And the phone conversation between Michael Adams at Mylan starts out by saying: Incident description. And it states that verbal notification received from quality director at Actavis Totowa that the FDA has requested a Class I recall of this lot of product.

Do you see that?

A Yes.

Q And what they're talking about here is product name. It goes into Digitek, .125, and goes through -- would you agree with me

that that is the double-thick lot, Lot 70924, Alpha 2?

A It's the lot, yes, we've been talking about all day.

Q And it goes on to say that the lot had been investigated for double-thick tablets by Actavis. The entire batch was visually inspected, and we heard the story of 15 suspect tablets were found out of approximately 4.8 million. The lot was then AQL'd and passed, released to MPI, and subsequently distributed by MPI.

Did you have an understanding that Mylan distributed that lot?

A Yes.

Q And when they say that a notification was received by the quality director at Actavis, who has that title?

A There were two. One was Dan Bitler. The other was Tony Castellazzo. I don't know -- my -- Tony Castellazzo typically did not interact with the customer, so the only other quality director would be Dan.

Q So as you sit here, if it was your

department, you would believe it was Dan Bitler that had to have this --

A If they're just referring to the title, I would.

Q Fair enough. It says: Actions taken: A conference call with quality director of Actavis was immediately held by MPI quality, procurement, and operations representatives. Actavis explained that this is part of a larger recall of products stemming from an on-site FDA inspection.

Would you agree with the language that the quality director of Actavis used, that it's part of a larger recall of products stemming from an on-site FDA inspection?

A I would qualify it a bit, but yes. I think there were other recall -- other products recalled as a result of the inspection, and I think he was just basically letting them know that this was an outcome of the FDA inspection.

Q And when you say "other products," we've agreed that it's all products that were made or manufactured at Totowa?

A Well, not at this particular point in time.

Q Not at that point in time?

A Right.

Q But as a result of the inspection, you agree that all products were recalled at Totowa?

A Eventually.

Q It goes on to say that Actavis committed to gather all relevant data and hold a conference call the next day, April 24th, to provide specific details so that we may take action to recall this lot.

Do you recall having -- or do you recall being a part of any conference calls with Mylan regarding the data of this lot or any Digitek information?

A Well, this actually sort of relates to the events we talked about earlier. We were originally intending to call -- to recall the one lot. And then on the 24th -- between this conversation and the 24th was that conversation between Mimi Remache and Robert Wessman where it became all lots.

So by the time we got to April 24th and talked with Mylan again, it had been expanded to all the Digitek lots, not just one.

Q Did the decision to expand it to all lots include the logic that there were serious deficiencies in the GMP department other than the double-thick pills?

MR. DEAN: Objection. She's already said that was -- she's testified fully on that, about a discussion between Mimi and Wessman, and she said she doesn't know what went on in that conversation.

MR. MILLER: Well, I'm talking about any conversation with anyone.

BY MR. MILLER:

Q Does the only conversation you've ever had with anyone regarding the recall of Digitek only include the double-thick lots, or would you have discussed the significant deviations from GMP that were found by the FDA?

A My discussions with FDA were

relative to the one lot. And on that particular day, as I had mentioned earlier, FDA inquired about contacting our CEO in Iceland. And after that conversation, I was told to recall all lots.

So I didn't have any conversation. I needed to scramble and recall all lots. So I didn't have a discussion with anybody about the pros and cons. It was pretty much dictated to me that we were doing this.

Q As the vice president of quality control and compliance at Actavis, would you agree that the recall of Digitek, if you're looking at the double-thick pills, that there was a larger issue of all the GMP violations that were found in the inspection; and then included in there were the double-thick pills?

MR. DEAN: Objection; miscategorizes her testimony.

Go ahead.

THE WITNESS: I can't say that. I would not agree to that. I think the Digitek issue was in itself an issue. I don't think it had anything to do with

anything else going on in the inspection except that they were not happy with what they had seen so far.

And so when the Digitek one came along, they took a harsher approach in looking at it and most likely due to the nature of the product, but that's just my opinion.

BY MR. MILLER:

Q Did they also take a harder look because of the significant GMP issues that were going on in the laboratory?

A Her -- no, it had nothing to do with the laboratory.

Q I'm sorry. Strike that.

A This particular observation had absolutely nothing to do with the laboratory.

Q Let me rephrase the question.

You agree that there were significant GMP deficiencies found in the quality control system?

MR. DEAN: Objection. That's been asked and answered about ten times.

MR. MILLER: Well, I'm trying

to get to another answer. I'm asking it again.

THE WITNESS: Erin's concern was that it didn't find a definitive cause. So her issue was, if you don't know what caused it, how -- perhaps you don't know it didn't happen with another batch.

BY MR. MILLER:

Q You're talking about double-thick pills?

A Correct.

Q I'm not talking about that. Set that aside.

She found significant deficiencies in GMPs with the quality control system?

A But what I'm saying to you is that's why I don't think that the Digitek had to do -- anything to do with GMP issues. I'm saying that based on what I heard as being Erin's concern was that we didn't -- that we released that batch.

She was not happy with -- she felt we could do more before making the decision to

release that batch. And she was complaining about the fact that you didn't find a cause, so you didn't -- you couldn't say that it didn't happen with another batch.

Q That's fine. Again, I'm not talking about the double-thick batch at all.

Of the other 65 or however many products there were, you agree that all those products were subject to the testing and results of the quality control system that had significant deficiencies; do you agree?

A Say that again.

Q Yes. There were significant deficiencies in the quality control system at Actavis; we've agreed with that. Do you -- right?

A Are we talking about Digitek and why it expanded to all lots?

Q No, we are not.

A We're not talking about that anymore?

Q No, we're not. We're not. No.

A I'm confused.

Q Okay. No, no, no. I'm talking

about --

A Now ask me the question again.

Q I'll start the same way I started last time.

The other products, the other 64 or 65 products, they were subject to a quality control system that had significant deficiencies with GMPs; correct? Do you agree with that?

A That was the view that FDA took.

Q What's different about Digitek? Why is Digitek not lumped in with those other 65 products?

A Because of the time frame that you're talking about. Digitek was in April, and the 65 products was in July.

Q I'm talking about the findings of the 4 --

MR. DEAN: Let her finish.

THE WITNESS: In April, we had no intention of recalling the other 65 products. In April, it was our intention to do the review by PAREXEL of the remaining products and be able to defend

to FDA keeping those products on the market.

That actually -- that course of events took place. PAREXEL did review those products. We had information to defend those products. We chose not to take that route because FDA would not let us proceed and resume manufacturing until we took action with the product that was remaining on the market. So the decision was made to bite the bullet and bring the rest of the product back. That's why the 65 products were recalled in July.

BY MR. MILLER:

Q So --

A If nothing ever happened with Digitek, all of it would have been recalled in July just like everything else because we were at a point where we stopped manufacturing.

And FDA would not even grant us a face-to-face meeting to discuss how to move forward until we took action with product in the distribution center and on the market. So we bit the bullet and we conceded and brought

everything back. That's the story. I'm sorry. I get -- I spent ages and ages trying to defend it, and we brought it all back anyway. So I'm very passionate about this topic.

BY MR. MILLER:

Q It is your testimony today that up to April 24th of 2008, the only product that was being discussed to be recalled was Digitek?

A No. It was Digitek and several of the stability-related out-of-spec products. And there's documentation with dates and commitments. And I put everything in writing, so it should be here somewhere, the exhibits that are referred to.

MR. MILLER: That's all the questions I have.

MR. DEAN: I've got a few questions.

THE VIDEOGRAPHER: We should probably go off the record, and I'll give you a new clip.

MR. DEAN: Oh, please. That

would be handy, I guess.

THE VIDEOGRAPHER: Off the record at 6:23.

(Discussion off the record.)

THE VIDEOGRAPHER: Back on the record at 6:26.

BY MR. DEAN:

Q Ms. Lambridis, as you know, my name is Richard Dean. I just have what I hope are a few questions for you.

I want to direct your attention to Exhibit 91. Do you have that in front of you?

A Yes.

Q And both Mr. Blizzard and Mr. Miller have asked you questions about the summary paragraph at the beginning, which relates to a 2007 inspection; correct?

A Yes.

Q Did Actavis pass that inspection?

A Yes.

Q And how can you tell that from the document?

A Because it says that the inspection was classified as VAI.

Q And I think you told I think it was Mr. Blizzard that meant voluntary actions indicated. But could you explain what "voluntary actions indicated" means?

A It means that although there were findings that were noted on the 483, that there were corrections that were promised and that the observations were not significant and that we were voluntarily taking action to correct them so there was no dispute over whether -- no dispute by the company -- the company was willing to modify whatever was found to correct it. And in some cases, it may have been corrected even before the close of the inspection.

Q That inspection covered all -- did that cover all the six areas you mentioned before?

A It indicates here that it covered five. It would not have covered packaging because they don't do packaging, so that would have been the sixth.

Q So the five areas that they were evaluating, the FDA gave you a good inspection

on all five areas; correct?

A Correct.

Q Now, as a consequence of that, was the company able to get new product approved?

A Yes.

Q And if the FDA had not given you a good rating or passed you, would the company have been able to get new product approved at that time?

A No, because prior -- prior to this 2007 inspection, the firm was under a warning letter. And then so usually under a warning letter, you would not get new approvals. And there were several that were being held up as a result of that.

So after the close of this inspection in September of 2007, they were basically -- we were basically given a clean bill of health, and then the approvals started to come through.

Q All right. Now, there's been testimony during the course of the day about certain drugs that had stability issues. You remember that testimony, do you not?

A Yes.

Q Was there ever a stability issue with Digitek?

A Not that I'm aware of.

Q Let's talk about the one lot that we've -- I want to go back and ask you a few questions about the lot that you spoke to Mr. Miller about. Is it fair to say in your discussions with Erin McCaffery that the only issue she ever addressed with you about that one lot was what we have called here today the double-thick issue?

A Correct.

Q Did she ever raise any other concerns about that particular lot with you other than double thickness?

A No.

Q Did she ever discuss any other lot that had been shipped out of the facility with you at any time during the course of your discussions with her, of Digitek?

A No. The majority of what was discussed related to this lot.

Q And was the discussion about double

thick you had, was it limited to this one lot that we've been talking about, 70924?

A Yes.

Q Do you know what a belt inspection is?

A Yes.

Q What is it?

A I can describe it.

Q Very briefly.

A It would be described as -- it's a terminology used for when you would visually want to inspect something. So there are firms that may actually have a belt that they put tablets on, but typically it means that the tablets are laid out perhaps on a table like this and inspected, of course not on the table but on trays or on liner paper, what you would normally put product on as product contact surface, clean area to inspect.

Q Is a belt inspection an accepted industry standard?

A It's accepted as a means for inspection, but it should not be a routine way of doing business. It's usually done on an

exception basis if there's an issue that warrants it.

Q The hour is late. I don't want to go through a lot of the documents that we've been through today. But you were shown a lot of documents after -- whose date was after July of 2008 with various comments about production at the facility and standards and goals and investigations. At that point there was no -- as of July 2008, there was no product being made at the facility any longer; is that correct?

A We ceased, yes, in July -- prior to July but definitely in July up until, I guess, whenever FDA came back and allowed them to manufacture.

Q So I'm thinking specifically about some of the -- kind of the production goals and targets that were referenced in some of those October and November documents. Those were just in hopes of getting back up to manufacturing status; correct?

A Those were part of the corrective action plan or the self-assessments that were

done that identified what activities we were going to be working on to put the facility in a position to be reinspected.

Q Those were your self-imposed standards as opposed to FDA's standards at that point; correct?

A Correct.

Q You were shown a number of different recall letters, drafts, final versions. And I think there was testimony about getting agreement for the recall letter. Who did you have to get agreement for -- agreement with for the recall letter before it was finalized?

A The main group would be FDA. They give the final okay. So it was the three -- well, the two companies and FDA.

Q In a usual situation where you're just manufacturing yourself and there wouldn't be a distributor like there was here, a company would need to get the approval of the FDA before it sent out a recall letter; right?

A Yes.

Q They'd have to agree as to the exact wording; right?

A Yes.

Q In this case, there were three parties that had to agree on the language; right?

MR. MILLER: I'm going to object. You're leading the witness.

MR. DEAN: I'm summarizing the testimony you guys have already gotten out.

BY MR. DEAN:

Q But who had to agree for this recall letter to go out?

Do it your way.

A The letter was -- the letter for digoxin was sent by Actavis to Mylan. So Mylan didn't necessarily have to agree with what was in our letter; but I believe they did participate, more so in the press release, more so -- Mylan participated more so in the press release than in the letter.

But FDA definitely weighs in and will change wording or ask for certain things to be put in or taken out of a recall letter.

Q Does the FDA have to approve the

exact words in a recall letter before it goes out?

A FDA has to give approval of a final draft, and then we would typically send them back whatever we send out.

Q You were asked a number of questions about good manufacturing practice and whether a violation of those might result in a conclusion that a product was adulterated. Do you remember that series of questions?

A Yes.

Q If a product is deemed adulterated, does that mean that it is unsafe?

A Not all the time.

Q Why not?

A Because as was pointed out in -- I believe when I was speaking to Mr. Miller, when he presented the citation from the Food, Drug, Cosmetic Act, that states that if you violate GMP, it considers a drug to be adulterated. But that violation of GMP could just be because -- it could be a paperwork issue and have nothing to do with the safety and efficacy of the drug. So there have

been -- historically in industry there have been recalls for GMP violations that have nothing to do with safety.

Q And here we -- I also want to go back. There's been reference during the course of the day to a company called PAREXEL; correct?

A Yes.

Q Did PAREXEL have anything to do with studying or being involved with Digitek?

A No. PAREXEL came on-site around the same time that this had already been in the works. So PAREXEL's scope was -- did not include Digitek because it was already being recalled.

Q And I wanted to go back to what Mr. Miller asked you right at the end of his questions and he got a time line from you. And I think you talked about there were certain drugs with stability issues; correct? There was a group of drugs with stability issues?

A Correct.

Q Digitek was not one of those drugs;

right?
A Correct.
Q Then there was Digitek.
A Right.
Q And then you said then -- what I just described king of took place in the April/May time frame. And then in July, there were 65 other drugs approximately?
A Yes. And there was a group in the middle there, another group.
Q And PAREXEL was dealing with those middle and those later groups in July; correct?
A Correct.
Q And I think you told us it was your belief -- I want to make sure I heard this correctly -- that there was no GMP violation ever found in regard to the batch of Digitek? Strike that.
Was it your testimony that there was no GMP violation found on any Digitek manufactured in 2007 and 2008?
A I want to be careful how I answer this. There was something that was presented

to me today which was on the 483 that was found by Kristy, who was another FDA investigator on-site. She joined the inspection later. And I don't know the detail around that issue. I can't recall all the detail around that issue.

With respect to the double thick, again, I believe in part of the earlier testimony, I had indicated that hindsight's 20/20. And, you know, could that situation have been handled better in terms of a judgment call? Yes.

But in most of the cases here, what FDA is citing as a violation, in some cases it's because, you know, something was investigated but not investigated to the extent that they would have liked to have seen it investigated or it was only a lab investigation and didn't extend to manufacturing. It wasn't a situation where it was a "do nothing."

And as I had pointed out, it's a fine line because the GMPs tell you that you need to do certain things, that you need to

investigate. It doesn't tell you how. It doesn't tell you to the extent. And so there are certain judgments that are made in putting procedures together. So I'm trying to put that in the context of my answer.

Q Let me ask it this way: Did Erin McCaffery want you to recall Digitek because there was a double-thick finding, or did she tell you she wanted it recalled because there was a GMP violation?

A Because there was a double-thick tablet.

Q Did she ever tell you -- did Erin McCaffery, just putting aside this note by Christine that you mentioned, did Erin McCaffery ever tell you there was a GMP violation with this particular lot of Digitek we've been talking about?

A Erin points to the fact that the double signature on the page where Dan signed multiple times as a GMP violation and that's just bad practice, but that's not the reason for recalling the batch.

Q Mr. Miller asked you a series of

questions about the lab in the context of the 2008 EIR. And I think you said that if I -- I want to go back to -- strike that.

Mr. Miller asked you about the lab in regard to the 2008 EIR. Did you have -- do you recall specific discussions with Erin McCaffery about her observations about the lab during that 2008 inspection?

A Yes.

Q What do you recall?

A There were several conversations with Erin about the lab. And as I indicated, she looked at the lab because the lab was already in the Riverview facility and -- it was a new lab -- and was happy with what she saw there.

She was -- also made several comments about how the lab had improved based on her knowledge of prior inspections because she had inspected there several times in the past, and she was also aware of the prior inspection that -- in 2006 that was mainly focused on the lab; at least most of the 483 items were focused on the lab.

Q So is it fair to say that her concern in the 2008 EIR inspection process was the QA group?

A Yes.

Q And she did not express a concern to you during all your interactions with her about the lab, did she?

A Correct.

Q Now, in the EIR -- and, again, it's Exhibit 91 and it's right there in front of you -- there are observations that are listed; correct?

A Yes. They typically would write the observations.

Q I'm just looking, for example, Page 48. Let's just turn to Page 48 as an example. Is the -- first of all, what is an observation generally?

A An observation is the investigator's -- what the investigator observed during their inspection.

Q Is an observation a finding of the FDA?

MR. MILLER: Objection; asked

and answered.

BY MR. DEAN:

Q Go ahead.

A The 483 document itself, the form, has a disclaimer on the top that basically states that it's the view of the investigator and not necessarily the opinion of the FDA.

Q And you said -- you told Mr. Miller that these observations, the actual language of the observation were pre-written; is that right?

A There's -- I can't remember the name of the computerized system that FDA has that it's currently using. But the investigators often complain about it, and so I became a little familiar with it.

There were complaints over the years about inconsistencies with how different districts and different investigators were approaching FDA inspections and that there was too much variance in opinion and so forth.

So in an effort to standardize it, they chose to standardize certain language and made it a requirement that when an

investigator is going to cite something on a 483, that they have to cite something that relates back to a specific GMP violation. And then what they did was they took those GMP sections and wrote standard language for each of it so that the investigator just pulls it and inserts it into the document. That's my best way of describing it.

Q And here's my question: Is every observation that's in Exhibit 91, the language, is every single observation pre-written language?

A The first part is -- from what I can tell is. It's the "specifically" part or the numbered parts, like the A, B, C parts are specific to the company. The others you would probably find very similar language in other people's -- or other companies.

Q Just so I'm clear, for example, the language on Page 48, Observation 5, you know -- I don't know how many observations there are, but Observations 1 through 5 through however many we get up to here, that language that's under observation, all of

those would be pre-written; correct?

A That is -- yes.

Q Mr. Miller asked you about Page 46 of that document, if you could turn to that. And he was asking you about some drugs where there were blend uniformity issues. Did Digitek ever have any consistent blend uniformity issues?

MR. MILLER: Objection.

BY MR. DEAN:

Q Go ahead.

A Not that I'm aware of.

Q Digitek is not listed on Page 46, is it?

A Actually, it is. But I can tell you why.

Q Okay. Go ahead.

A There was a discussion about blend uniformity specifications. And I don't know where we would find it in here.

Q Do you remember what the discussion was?

A Right. Blend uniformity specification -- blend uniformity is -- you

need to establish -- it's a requirement that you establish that your blends are uniform. You base that -- your specification on your finished-product specifications.

But over the years, the manner in which you do that testing -- sampling and testing has changed, so there's been recent guidance documents that were issued telling you -- giving you more leeway in setting the blend specifications.

And what had happened during this inspection is that Erin and Kristy had both noted that certain specifications for blends had changed. And when they questioned it, it was the outcome of either letters from FDA indicate -- for new products that were being approved indicating that you set the specifications differently and other conversations with FDA.

And this actually points to something I was mentioning earlier where we were getting one set of information from the center, which is Washington, D.C., office of FDA. And then the local district folks were

coming in and questioning it, but it was their own agency. So we had sort of a -- Erin had her opinion about how it should be done, and we were following direction coming out of the Washington, D.C. office.

Long story, but in this particular case, it says here: Despite noted blend uniformity issues, in-process blend uniformity specifications for many products were changed from individual RSD to average. Current in-process blend specifications for the following products are listed.

So that -- digoxin is listed in that list because of that issue and is listed in this list by FDA. We did not put digoxin in this list.

Q This is a list for the --

A Where the specifications had changed.

Q Had changed, okay. So let's go back to where we started. As far as that, there were some products, I take it from your testimony today to Mr. Miller, where there had been blend uniformity issues; correct?

A Yes.

Q And is it fair to say that Digitek was historically not one of those in that category?

A To my knowledge, correct.

MR. DEAN: I think that's all I have. Thank you.

MR. MILLER: I've got a couple follow-up.

MR. DEAN: Do you want to switch?

MR. MILLER: No. That's fine if that's okay with you.

MR. DEAN: Sure.

BY MR. MILLER:

Q Ma'am, you were just asked about out of specifications for blend uniformity, specifically Digitek. And the section that we're looking at in Exhibit 91 was the list of products on Page 46.

And if you turn pages backwards, you'll notice that this is a write-up that goes to Observation 4. Would you agree with that? You can go backwards page by page until

you get to Observation 4.

A Well, Observation 4 had several parts.

Q Agreed. But would you agree with me that this is a part of Observation 4, what we're looking at, the list on Page 46? Is it part of the write-up for Observation 4?

A Well, 4c. If you look at 4C, it says: Although approximately -- blank -- products were temporarily discontinued due to blend and/or content uniformity issues, there was no scientific rationale provided for the change of in-process blend uniformity specs.

MR. MILLER: Yes, ma'am. And I object because it's not responsive and I move to strike.

BY MR. MILLER:

Q My question is very simple. Is it part of Observation 4, not so much the content of what it says, but this is a continuation of Observation 4; is that a fair statement?

A 4c.

Q Yes. We --

A Because 4a --

Q Right.
A -- is substantiated here.
Q 4c is part of --
A And then 4b is substantiated here. And then 4c is substantiated here.
Q Is 4c part of 4?
A Yes.
Q Thank you. And you agree that Observation 4 starts out with the GMP violation which we discussed at length and which boils down to -- or "the template" is the term you like to use, determinations of conformance to appropriate written specifications for acceptance are deficient for in-process materials.

Do you agree that Observation 4, once again, is a violation of a GMP?
A Which part?
Q The sentence I just read.

MR. DEAN: That's an observation.

THE WITNESS: The sentence you read is an observation.

BY MR. MILLER:

Q Is that observation outlined in the finding of an FDA inspector for a violation of a GMP as described?

A That's the violation she believe -- that's the GMP regulation that she believes is being violated.

Q Thank you. And the specific example goes to three lots of Digitek that were not the double-thick lots that had issues with out of specifications during blend uniformity testing; do you agree?

A That's the -- one of the examples that she uses here, yes.

Q One of them.

A Correct.

Q And going to that -- well, you were just asked by Mr. Dean about pre-written observations. You'd agree with me that these pre-written observations don't wind up on a report unless they find a violation; they're triggered by a violation; correct?

MR. DEAN: Object to the form.

Go ahead.

THE WITNESS: The requirement for the investigator is if they have a finding, they have to tie it to what they believe to be the GMP regulation that it's violating.

BY MR. MILLER:

Q If there were no violations of blend uniformity or out of specifications with stability or blend uniformity, then there would be no pre-written template; is that correct?

A Just to be clear, blend uniformity is not a -- there's nowhere in the GMPs that says you have to do blend uniformity --

Q Okay.

A -- specifically. I believe her issue here had to do with -- okay. She's talking about in process. I'll take that back. Different context. Okay.

Q But in the context of how she uses it, she had to find that violation before the pre-written language was used; correct? The pre-written language just don't show up; she's got to find a violation first; correct?

A She has a finding; and, yes, in order for her to -- in order for her to put it on the -- the criteria would be for her to tie it back. If it's not tied back to a GMP regulation, then the chances are that her supervisor won't allow her to cite it.

Q But the pre-written language that we've discussed at length is not an option to her; once the violation is found, then she decides what pre-written language fits the observation; correct?

A Once the observation is found, she has to find the pre-written language, correct.

Q Thank you. You were asked if you passed the -- or Actavis passed the 2007 inspection. I believe you said that you did; correct?

A Yes.

Q But you agree that there were GMP violations observed during that inspection?

A There were 483 observations at the end of that inspection. It said so in this report.

Q Right. And those 483 observations,

you would agree, were GMP violations?

A I'm going to give you the same answer I've been giving for everything. It's the investigator's observations that they believe are violations of GMP.

Q Thank you. Did you pass the May 2008 inspection?

A No.

Q And there are different levels of -- would you say you failed that inspection? Is that one way to put it?

A That inspection was not VAI.

Q It was not voluntary?

A It was OAI.

Q Which is?

A I think if it's -- it might be in here. I don't know. OAI is official action indicated, which means that more severe action was taken as a result of that inspection.

Q And if you're going to use the term you passed the one in 2007, would you agree with the term you failed the one in 2008?

A Yes.

Q Does a failed inspection result in

an unsafe product?

A Not always.

Q Not always because you said -- correct me if I'm wrong -- that sometimes a recall can be done because of paperwork issues. Would you agree with me that the recall for Digitek had nothing to do with paperwork issues?

A For the one batch, yes. For all batches, no.

MR. MILLER: That's all I have.

MR. DEAN: Pete, it will take me one and a half minutes here. Then we'll be done.

BY MR. DEAN:

Q I want to direct you back. Mr. Miller asked you a couple questions about Observation 4. Is it fair to say that the observations in 4a and 4c are two different -- two different fact patterns being discussed?

A Yes.

Q And it's the fact pattern in c that you testified is as a result of specifications being changed over the course of time; is that

correct?

A Yes.

Q And so I go back to my question. This took place in -- these observations took place in 2008, correct, that we're looking at in --

A Yes.

Q Historically before 2008, were there blend uniformity issues with Digitek?

A Not that I'm aware of.

MR. DEAN: Thank you.

MR. MILLER: That's it. Thanks for your time.

THE VIDEOGRAPHER: That concludes this videotaped deposition. The time is 7:01.

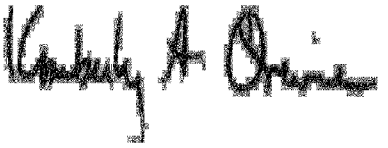
(Whereupon the deposition adjourned at 7:01 p.m.)

- - -

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, PHYLLIS A. LAMBRIDIS, have the opportunity to read and sign the deposition transcript.



KIMBERLY A. OVERWISE
Certified Realtime Reporter
Notary Public
Dated: January 29, 2010

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

E R R A T A S H E E T

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ACKNOWLEDGMENT OF DEPONENT

I, PHYLLIS A. LAMBRIDIS, do hereby certify that I have read the foregoing pages, 1-396, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____ _____

PHYLLIS A. LAMBRIDIS DATE

Subscribed and sworn
to before me this
____ day of _____, 2009.

My commission expires:_____

_____
Notary Public

LAWYER'S NOTES

PAGE	LINE	